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Approvals	Approvals						
Approvals	Name	Title	Signature	Date			
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Doc Number: D0000003422 Name: Product security standard assessment

Revision: AB

PRODUCT SECURITY STANDARD ASSESSMENT - Header

Section 1. Identifying Information (enter N/A for any items that do not apply)						
Document Number	D001020014	Author	Deepak Sharma			
Document Revision	01	Project Lead	Akhil Gupta			
Project Name	SmartMedic Phase II	Division/Function	NPD			
Project (DHF) Number	SGTC-NPD-000-02	Business Unit	R&D			
Description of Medical Device/System in scope	SmartMedic -001-02-A-00-00-00 SmartMedic is an AC powered (with AC to DC adaptor) device intended for use on Hospital Beds. It is designed to provide improved patient care in the hospital facility. The device is secured in place on top of the bed frame and under the bed's mattress. The device can provide patient weight, turn indication and share information with authorized hospital nurse station. The system shares and displays information on hospital's Nurse station through cloud application. The device also supports functionality for placing x-ray cassette without moving the patient on bed.	Comments				
Change History (Rows may be adde	d)					
Revision	Comment	Date	Author			
00	Initial Release DR1-4 Document was reviewed but not approved and archived, thus archiving	30-Aug-21	Deepak Sharma			
01	-Document updated as per DR5-7 requirement - SmartMedic Part number corrected (Typo error) in Header Tab: Description of Medical Device/System in scope -"Rationale for not using Traceability reference if using" updated in sheet Capabilities Assessment Sheet-"Traceability Reference" updated in sheet Security Controls Assessment -"Traceability Reference" updated in Sheet Privacy Controls Assessment	8-Apr-22	Deepak Sharma			

Form Instructions

- 1. Complete Identifying Information (Section 1). Keep information up to date if document in revised. Use of Change History section is optional unless required by local procedure. Note: The Table of Contents below explains the purpose of each worksheet in this file. Only the first three worksheets must be completed. The others are for reference.
- 2. Complete the Capabilities Assessment worksheet, following instructions on that page.
- 3. Complete the Security Controls Assessment worksheet, following instructions on that page.
- 4. Complete the Privacy Controls Assessment worksheet, if required.
- 5. Refer to D0000061606 for requirements concerning when and how this PSSA is to be used in the overall software design process.

Table of Contents						
Worksheet	Explanation	Form/Reference				
Header	Document information, product identification, revision history	Form				
Capabilities Assessment	Form on which to select security level, relevant capabilities, and whether privacy by design elements are relevant	Form				
Security Controls Assessment	Form on which to select applicable security controls, or to justify not implementing them in the design	Form				
Privacy Controls Assessment Form on which to select applicable privacy controls, or to justify not implementing them in the design		Form				
Logic Tables	Formula tables used to determine which controls and control enhancements must be assessed based on selected standard, selected capabilities, and security level	Reference				
Impact Levels	Guidance for selecting Potential Impact	Reference				
Capabilities and MDS2	Chart listing the explanations of each security capability, and the MDS2 questions that correspond to each	Reference				
Controls and Guidance	Details concerning the NIST security controls, including additional guidance, control enhancements, and Stryker-specific guidelines	Reference				
Privacy BR	Full text of the Privacy by Design baseline requirements associated with each family and sub-element of the Privacy by Design framework	Reference				

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PRODUCT SECURITY STANDARD ASSESSMENT - Capabilities Assessment					
DHF Reference:	SGTC-NPD-000-02				
Product/Entity:	SmartMedic - 001-02-A-00-00-00 SmartMedic is an AC powered (with AC to DC adaptor) device intended for use on Hospital Beds. It is designed to provide improved patient care in the hospital facility. The device is secured in place on top of the bed frame and under the bed's mattress. The device can provide patient weight, turn indication and share information with authorized hospital nurse station. The system shares and displays information on hospital's Nurse station through cloud application. The device also supports functionality for placing x-ray cassette without moving the patient on bed.				

Section 2. Potential Impact Selection (See Impact Levels tab)						
Category	Rationale for Selection	Selection				
Confidentiality	Patient data is not stored in system. Identification of patient is not possible.	Low				
Integrity	Limited impact even if the weight data is modified by unauthorized user. Only impacted system will be Nurse Station and any	Low				
Availability	Limited impact even if the weight or position data is not available on Nurse Station or the external system. To be included in SQ	Low				
	OVERALL Potential Impact Level	Low				

Instructions for this worksheet

- Instructions for this worksheet
 1. Refer to D0000061606 for requirements related to the PSSA.
 2. Complete Section 2, selecting potential impact and entering rationale.
 3. Select Yes/No for to indicate applicability of each capability listed in Section 3.
 4. Enter rational for any capability determined not to apply.
 5. Complete Section 4 to determine if Privacy by Design requirements apply.
 6. Proceed to complete the Security Controls Assessment worksheet.
 7. For each applicable capability, once the capability has been added to the design inputs for the product, enter traceability reference number (e.g. the design inputs document number).

AAMI,	/IEC TIR80001-2-8:2016 for relatio	nship of each capability to NIST security controls. Click the Capability name to see additional explanation and a list of related MDS2 questio	ns.	
ID	Capability	Requirement Overview		Rationale for not using / Traceability reference if using
10	AUTOMATIC LOCOFE (ALOF)	System shall provide automatic logoff after a period of inactivity	Yes	SRS D001020097 - 2.1.2.5 The Application shall allow the user to b logged out if the session has ended or after 8 minutes of inactivity.
20		System shall provide audit controls documenting who is doing what with health data	Yes	SRS D001020097 - 2.23.2 - Audit logs
		The system shall provide role based controlled access to health data and functions - access to be provided only as necessary to		SRS Item (Applicable to NurseStation, Tablet Application) : Single Acc
30	AUTHORIZATION (AUTH)	perform the tasks required consistent with intended use	No	with hospital code. No need of authorization
40	CONFIGURATION OF SECURITY FEATURES (CNFS)	System shall provide the Hospital system administrator the ability to configure the products security capabilities	No	Relevant Security controls for the NurseStation and the Tablet Application are identified within this document. Any controls which may be relevant for any customer (and hospital 17) and which are beyond the trurst boundaries of the Stryker system will be adressed the SOM (Security Operations Manual - D001020115)
50	UPGRADES (CSUP)	The system shall provide the ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade device's security patches	Yes	D001020115: Security Operations Manual -19. Cyber Security Produ Upgrades: For tablet, the product upgrade shall be provided in the for of Application installer files and will be done by Stryker Service perso Nucres station is a web application which can be taken care by the ser admin.
60	HEALTH DATA DE- IDENTIFICATION (DIDT)	The system shall provide the ability to directly remove information that allows identification of a person	Yes	SRS D001020023 - 2.13.2 - System shall store patient id in anonymiz fashion.
70	DATA BACKUP AND DISASTER RECOVERY (DTBK)	The system shall have an integral data backup capability to recover after damage or destruction of device data, hardware or software	Yes	SRS D001020097 - 2.19.1 - The System shall use backup mechanism provided by Azure.
80	EMERGENCY ACCESS (EMRG)	The system shall provide users the ability to access private data in case of an emergency that requires immediate access to private data	No	The Intended Use does not requires this arrangement for private accounts of the contract of th
90	HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU)	The device shall ensure the integrity of stored data with implicit/explicit error detection/correction technology	No	NoPHI (personal health information) stored
100	MALWARE DETECTION/PROTECTION (MLDP)	The system shall support the use of anti-malware mechanism	Yes	SRS D001020024 - 2.17.6 The Application shall support the use of ant malware mechanism D001020115: Security Operations Manual- 23. Malware Detection/Protection SYK donot have control over the user desktop for Nursing application
110	NODE AUTHENTICATION (NAUT)	The system shall provide node authentication to ensure that only known devices can connect with each other and share data	Yes	SRS D001020024 - 2.17.8 - Only Stryker made/ authenticated device should be able to communicate with SM device and tablet. Bluetooth Authentication on device, DeviceID act as the key for devic authentication Tablet provisioning on IOT Hub with tokens (Applicable to SmartMed device, Tablet and Cloud connections)
120	PERSON AUTHENTICATION (PAUT)	The system shall provide the ability to authenticate users	Yes	SRS D001020024 - 2.17.3 :The application shall provide access to authorized users using authentication code D001020115: Security Operations Manual - 4. User Account Management Nurse station has authentication provided by entering hospital id. Additionaly application has the configuration options to monitor inactivity.
130	PHYSICAL LOCKS (PLOK)	The system components that maintain private data shall be physically secure	Yes	Applicable to Tablet- Physical enclosure to secure the tablet. D001020115: Security Operations Manual - 27. Physical Locks
140	ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)	The system software development plan shall address security support of 3rd party components throughout system life cycle	Yes	Software Development Plan: D001020020 Applicable to SmartMedic Device, Tablet Application and Nurse Stati application D001020115: Security Operations Manual - 24. Roadmap for Third Party Components in Device Life Cycle
150	SYSTEM AND APPLICATION HARDENING (SAHD)	System shall provide hardening features to guard against cyber attacks and malware	Yes	D001020115: Security Operations Manual - 26. System and Applicati Hardening D001020037 Penetration Testing Protocol reference for application hardening Applicable to Tablet Application.
160	SECURITY GUIDANCE (SGUD)	The system service/user manuals shall provide security guidance for operators and administrators	Yes	D001020115: Security Operations Manual Applicable to SmartMedic Device (Bluetooth and wifi connection), Tablet Application, Nurse Station and Hospital's WiFi network.
170	HEALTH DATA STORAGE CONFIDENTIALITY (STCF)	The system shall establish technical controls to mitigate the potential for compromise to the integrity and confidentiality of health data stored on product or removable media	Yes	SRS D001020023 - 2.13.2 - System shall store patient id in anonymi fashion. D001020115: Security Operations Manual - 25. Health Data Storage Confidentiality
180	TRANSMISSION CONFIDENTIALITY (TXCF)	The system shall ensure confidentiality of transmitted health data	Yes	D001020115: SOM (Wifi Security WPD-2 PSK) - 16.Transmission confidentiality and integrity Applicable to Smartmedic device, Tablet and Nurse Station
	TRANSMISSION INTEGRITY	, , , , , , , , , , , , , , , , , , ,	Yes	D001020115: SOM (Wifi Security WPD-2 PSK) - 16.Transmission confidentiality and integrity

Section 4. Privacy by Design filtering questions						
	ID	Question	Note	Answer		
	200		Answer yes if the device has software with the capability to collect and process personal information; e.g. a defibrillator that collects and stores a patient name and vital signals (e.g. ECG) and is connected to a cloud system.	No		
		Is there any processing of PHI or PI as part of the product life	The product life cycle could comprise the creation of the product (e.g. planning for patient specific implants), its distribution, sale and/or maintenance.	No		

Note: After this Capabilities Assessment page is completed, the remaining Controls Assessment worksheets will indicate the security and privacy controls that must be assessed.

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PRODUCT SECURITY STANDARD ASSESSMENT - Security Controls Assessment

 $\frac{\text{DHF Reference:}}{\text{Product/Entity: e}} \text{ bed frame and under the bed's mattress. The device can provide patient weight, turn indication and share information and the bed's mattress.}$

Instructions for this worksheet

1. Refer to D0000061606 for requirements related to the PSSA. If privacy is in scope based on answers to questions in the Capabilities Assessment worksheet, the Privacy Controls Assessment worksheet must also be completed.

1. Refer to D0000061606 for requirements related to the PSSA. If privacy is in scope based on answers to questions in the Capabilities Assessment worksheet, the Privacy Controls Assessment worksheet must also be completed.

2. Review Section, so, noting which security controls indicate that assessment is required. Links in the sections may be used to determine the meaning of each control and control enhancement.

Note: When the "Y" in the Assessment Required column is followed by one or more numbers, it means that the Control Enhancement(s) of the same number(s) must be assessed in connection with the Security Control.

Note: The Logic Table worksheet demonstrates how the selected capabilities and the potential impact level determine which controls and control enhancements must be assessed.

3. In Section 5 indicate which controls will be included in the product design ("Yes" means that the control and any listed control enhancements will be incorporated). Enter justification for any assessment-required control that will not be included.

4. Clarification notes may be added to explain the method or extent to which the item will be incorporated.

5. Once a selected control is added to the software requirements, update the Traceability Reference field with traceability information (such as the number of the SRS document).

	Assessment Required?		Justification if not using NIST control and applicable	
Controls (click control name for details)	Y = Control must be assessed; Number(s) refers to control enhancement(s) that must be assessed	Include?	control enhancement(s)/ Clarification notes	Traceability Reference
AC-1 Access control policy and management	Y	No	Unique id provided for access to hospital, hence no access control	SOM D001020115 - Section 05. Access control policy and management
AC-2 Account management	Y	No	Unique id provided for access, no multiple roles/subjects/accounts	SOM D001020115 - Section 04. User Account Management
AC-3 Access enforcement	N	No	Unique id provided for access, no multiple roles/subjects No seperation of duties planned in this product. All the duties are	N/A
AC-5 Separation of duties	N	No	handeled by Stryker service person	N/A
AC-6 Least Privilege	N	No	Unique id provided for access, hence no privileges are accounted	N/A
AC-7 Unsuccessful logon attempts	Y	Yes		SRS D001020097 - 2.1.2.1.1 Invalid email or password, only 3 attempts left.
AC-8 System use notification	Y	No	NS application runs on a system owned by HDO. Hence no control on the notifications	N/A
AC-11 Session lock	N	Yes		SRS: D001020097 - 2.1.2.5 The Application shall allow the user to be logged out if the session has ended or after 8 minutes of inactivity.
AC-12 Session Termination	N N	No	Session gets temporarily locked/disabled, wont get terminated. No session termination enabled in this product.	N/A
AC-14 Permitted actions without identification or authentication	Y	No	Components in the product cant be accessed without authentication.	N/A
AC-17 Remote access	Y	No	No remote access enabled for any components in the product	N/A
AC-18 Wireless access	Y	Yes		SOM: D001020115 - Section 22. Cryptographic Protection & Management, handshaking mechasim to use wifi
AC 10 Access control for mobile decises	V	Vaa		SOM D001020115 - Section 05. Access control policy and management
AC-19 Access control for mobile devices	Y	Yes	No information directly shared between the components with out	
AC-21 Information sharing	N	No	provisioning No database/storage is present in the system and hence no data	N/A
AC-23 Data mining protection	N	No	mining No authorization in scope for this system. Hence no access control	N/A
AC-24 Access control decisions	N	No	decisions	N/A SOM D001020115 - Section 06. Security
AT-1 Security awareness and training policy and procedures	Y	Yes		awareness training SOM D001020115 - Section 06. Security
AT-2 Security awareness training	Y	Yes		awareness training
AT-3 Security training	Y	No	Unique id and hence no multiple roles associated with the current system.	N/A
AU-1 Audit and accountability policy and procedures	Y	No	Product is a combination of stryker & hospital components. Hence no global audit policy and procedure can be established	N/A
AU-2 Audit events	Y	Yes		SRS D001020097 - 2.1.2.1.1 Invalid email or password, only 3 attempts left.
All a control of the	Y	V		SRS D001020097 - 2.1.2.1.1 Invalid
AU-3 Content of audit records	v v	Yes	Audit logging has miminal events. No constraints on the storage	email or password, only 3 attempts left.
AU-4 Audit storage capacity	•	No	capacity. Admin App is not hosted on a simple (resource constrained - H/W,	N/A
AU-5 Response to audit processing failures	Y	No	Memory) device No need to review the audit log. Any malfunctioning observed can be handled through Service Manual Document	N/A
AU-6 Audit review, analysis and reporting AU-7 Audit reduction and report generation	Y N	No No	No need of audit data mining and reduction	N/A N/A
AU-8 Time stamps	Y	Yes		SRS D001020097 - 2.1.2.1.1 Invalid email or password, only 3 attempts left.
				SRS D001020023 - 2.13.3 - Azure portal shall have authorized access.
AU-9 Protection of audit information	Y	Yes		
AU-10 Non-repudiation	N	No	Audit generation is incorporated in the NS admin application which runs with restricted access. No chances of repudiation.	N/A
AU-11 Audit record retention	Y	No	Audit generation is incorporated in the NS admin application which runs with restricted access	N/A
AU 12 Audit annualing	V	Yes		SRS D001020097 – 2.1.2.1.1 Invalid email or password, only 3 attempts left.
AU-12 Audit generation	N N	No		N/A
AU-13 Monitoring for information disclosure AU-14 Session audit	N	No	Audit generation is incorporated in the NS admin application which runs with restricted access	N/A
AU-15 Alternate audit capacity AU-16 Cross-organizational auditing	N N	No No	WALL COLLEGE SELESS	N/A N/A
CA-7 Continuous monitoring	Y	No	No security controls and information risk associated with the system. Hence continuous monitoring is not required.	N/A
				,
CM-1 Configuration management policy and procedures	Y	No		N/A
CM-2 Baseline configuration	Y	No	No security controls and information systems present and any system specific configuration is not maintained	N/A
CM-3 Configuration change control	N N	No		N/A
CM-4 Security impact analysis	Y	No	1	N/A
			1	N/A
CM-5 Access restrictions for change	N	No	None of the components in the product have configurable/customizable configuration settings (for ex: registry settings, account, file, directory permission settings, settings for	SOM D001020115 - Section 11. Configuration settings
CM-6 Configuration settings	Y	No	functions, ports, protocols, services, and remote connections)	
			No multiple functions/services associated with the product. Hence	I



Controls (click control name for details)	Assessment Required? Y = Control must be assessed; Number(s) refers to control enhancement(s) that must be assessed	Include?	Justification if not using NIST control and applicable control enhancement(s)/ Clarification notes	Traceability Reference
CM-9 Configuration management plan	N	No	No such maintenance/requirement of configuration plan for this product	N/A
CP-1 Contingency planning policy and procedures	Y	No	Product is a combination of stryker & hospital components. Hence no global audit policy and procedure can be established	N/A
and the state of t			, , , , , , , , , , , , , , , , , , , ,	SOM D001020115 - Section 08.
CP-2 Contingency plan	Y	Yes		Contingency Plan Testing, Maintenance and Training
				SOM D001020115 - Section 08. Contingency Plan Testing, Maintenance
CP-3 Contingency training	Y	Yes		and Training
				SOM D001020115 - Section 08. Contingency Plan Testing, Maintenance
CP-4 Contingency plan testing CP-6 Alternate storage site	Y N	Yes No		and Training N/A
CP-7 Alternate processing site	N	No	No alternate site required for storage & processing for this product	N/A
CP-8 Telecommunications services CP-9 Information system backup	N Y	No No	No telecommunications services required in this product No storage is included in this product, hence no need of backup	N/A N/A
CP-10 Information system recovery and reconstitution	Y	No	No recovery and reconstitution plan required in the product	N/A
			Sufficient security is provided, no need to have additional/altervative security items beyond the standard	
CP-13 Alternative security mechanisms IA-1 Identification and authentication policy and procedures	N V	No No	employed methods for hospital environment.	N/A
IA-2 Identification and authentication (organizational users)	Y + (1) (12)	No		
IA-4 Identifier management IA-5 Authenticator management	Y Y+(1)(11)	No No	Assigning to an individual a role or group is out of the scope.	
IA-7 Cryptographic module authentication	Y	No	Unique id is provided for authentication. Identification based on individuals is not provided. No need of	SOM D001020115 -Section 04. User Account Management
IA-8 Identification and authentication (non-organizational users) IA-9 Service identification and authentication	Y + (1) (2) (3) (4) N	No No	individual authentication & management.	
IA-10 Adaptive identification and authentication	N	No		
IA-11 Re-authentication	N	No		
IR-1 Incident response policy and procedures	Y	Yes		Incident management for the complete Smart Medic environment/platform
process party and process to				
IR-2 Incident response training	Y	Yes		SOM D001020115 - Section 07. Incident Management, Response, Training,
IR-3 Incident response testing IR-4 Incident handling	N V	No Yes	No Incident response testing required for this product	Testing, Handling, Monitoring & Reporting
IR-5 Incident monitoring	Y	Yes		1
IR-6 Incident reporting IR-7 Incident response assistance	Y Y	Yes Yes		(once it is on the market) is defined within the Corporate procedure -
IR-8 Incident response plan	Y	Yes		D0000003113 - Product Security Post Market Management.
IR-9 Information spillage response	N	No	No classified or sensitive information in the product. Hence no case of information spillage	
			No need to have an integrated team in this product for security	
IR-10 Integrated information security analysis team MA-1 System maintenance policy and procedures	N Y	No Yes	analysis	
MA-2 Controlled maintenance	v	Yes		
MA-3 Maintenance tools	N N	No	No maintenance tools are being employed in this product.	System maintenance for the Tablet (once it is on the market) is defined
MA-4 Nonlocal maintenance	Y	Yes		within the Corporate procedure SOM D001020115 - Section 10. System
MA-5 Maintenance personnel	Y	Yes		Maintenance
	N	No	It handeled as a part of Contingency plan. No need to consider here.	
MA-6 Timely maintenance MP-1 Media protection policy and procedures	Y	No	Product doesnt contain any digital/non-digital media. Hence no	N/A
MP-2 Media access MP-4 Media	Y N	No No	need to consider media protection. This product doesnt use any kind of media handelling/storage devices such as diskettes,	N/A N/A
MP-7 Media use	Y	No	magnetic tapes, external/removable hard disk drives, flash drives,	N/A
MP-8 Media downgrading PE-1 Physical and environmental protection policy and procedures	N V	No No	compact disks, and digital video disks, paper and microfilm.	N/A N/A
PE-2 Physical access authorizations	Y	No		N/A
PE-3 Physical access control	Y	Yes	The management of physical security aspects of the HDO's IT	SOM D001020115 - Section 27. Physical locks
PE-4 Access control for transmission medium	N N	No No	system, networks and other configuration items is a key responsibility of the HDO's IT network management.	N/A
PE-5 Access control for output devices PE-6 Monitoring physical access	Y	No	- responsibility of the fibo 3 11 network management.	
PE-9 Power equipment and power cabling PE-18 Location of information system components				N/A N/A
PE-18 Location of information system components	N N	No	1	N/A N/A
	N N	No No	-	N/A
PL-1 Security planning policy and procedures		No	N/A	N/A N/A
PL-1 Security planning policy and procedures	N		N/A	N/A N/A N/A N/A Security planning and information security program plan are shared
PL-1 Security planning policy and procedures PL-2 System security plan	N	No	N/A	N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities:
PL-2 System security plan	N	Yes Yes	N/A	N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for
	N	No Yes		N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the designedevelopment and
PL-2 System security plan PL-4 Rules of behavior	Y Y	Yes Yes	N/A N/A	N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered
PL-2 System security plan	N	Yes Yes	N/A	N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: [1] Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of
PL-2 System security plan PL-4 Rules of behavior	Y Y	Yes Yes	N/A N/A	N/A N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities.
PL-2 System security plan PL-4 Rules of behavior	Y Y	Yes Yes	N/A N/A Hospitals doesn't require security concept of operations	N/A N/A N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities. (2) Application specific security planning: The PSSA, the security
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations	Y Y Y N	Yes Yes No	N/A N/A	N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities. (2) Application specific security planning: The PSSA, the security processed of the procedures and the PS risk analysis
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations	Y Y Y N	Yes Yes No	N/A N/A Hospitals doesn't require security concept of operations	N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities. (2) Application specific security planning: The PSSA, the security planning: The PSSA, the security architecture and the PS risk analysis define application specific security controls which shall be implemented in
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations	Y Y Y N	Yes Yes No	N/A N/A Hospitals doesn't require security concept of operations	N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities. (2) Application specific security planning: The PSSA, the security planning: The PSSA, the security architecture and the PS risk analysis define application specific security controls which shall be implemented in the application and considered in accompanying material (eg service
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture	Y Y Y N N	Yes Yes No Yes	N/A N/A Hospitals doesn't require security concept of operations N/A	N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities. (2) Application specific security planning: The PSSA, the security planning: The PSSA, the security architecture and the PS risk analysis define application specific security controls which shall be implemented in the application and considered in accompanying material (e.g. service manual)
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan	Y Y Y N N	Yes Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A	N/A
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture	Y Y Y N N	Yes Yes No Yes	N/A N/A Hospitals doesn't require security concept of operations N/A	N/A
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan	Y Y Y N N	Yes Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A	N/A
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan	Y Y Y N N	Yes Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A	N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities. (2) Application specific security planning: The PSSA, the security planning: The PSSA, the security architecture and the PS risk analysis define application specific security controls which shall be implemented in the application and considered in accompanying material (e.g service manual) (3) Customer specific provisions: The SOM establishes application specific security controls and guidance to be considered by the HDO for his security program planning purposes
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan PM-9 Risk management strategy	N Y Y Y N N N Y	Yes Yes Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A N/A	N/A N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities. (2) Application specific security planning: The PSSA, the security planning: The PSSA, the security architecture and the P5 risk analysis define application specific security controls which shall be implemented in the application and considered in accompanying material (e.g. service manual) (3) Customer specific provisions: The SOM establishes application specific security controls and guidance to be considered by the HDO for his security program planning purposes SOM D001020115 - 3.5 System Security Context and Intended Environment SOM D010201115 - 3.5 System Security
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan PM-9 Risk management strategy PM-12 Insider threat program	N Y Y Y N N N Y Y Y	Yes Yes No Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A N/A N/A	N/A N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification roles & responsibilities. (2) Application specific security planning: The PSSA, the security planning: The PSSA, the security architecture and the P5 risk analysis define application specific security controls which shall be implemented in the application and considered in accompanying material (e.g. service manual) (3) Customer specific provisions: The SOM establishes application specific security controls and guidance to be considered by the HDO for his security program planning purposes SOM D001020115 - 3.5 System Security Context and Intended Environment SOM D001020115 - 3.6 Security awareness training SOM D001020115 - 20. Security
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan PM-9 Risk management strategy	N Y Y Y N N N Y	Yes Yes Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A N/A	N/A
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan PM-9 Risk management strategy PM-12 Insider threat program	N Y Y Y N N N Y Y Y	Yes Yes No Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A N/A N/A N/A	N/A
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan PM-9 Risk management strategy PM-12 Insider threat program PM-14 Testing, training and monitoring	N Y Y Y N N N Y Y Y	Ves Yes Yes Ves Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A N/A N/A N/A N/A As the product is to be sold in India, there is no requirement for	N/A N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the designedevelopment and post market surveillance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities. (2) Application specific security planning: The PSSA, the security planning: The PSSA, the security architecture and the P5 risk analysis define application specific security controls which shall be implemented in the application and considered in accompanying material (e.g service manual) (3) Customer specific provisions: The SOM establishes application specific security controls and guidance to be considered by the HD0 for his security program planning purposes SOM D001020115 - 35 System Security Context and Intended Environment SOM D01020115 - 35. Security awareness training SOM D01020115 - 20. Security Program Integration
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan PM-9 Risk management strategy PM-12 Insider threat program PM-14 Testing, training and monitoring	N Y Y Y N N N Y Y Y	Ves Yes Yes Ves Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A N/A N/A N/A N/A As the product is to be sold in India, there is no requirement for	N/A
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan PM-9 Risk management strategy PM-12 Insider threat program PM-14 Testing, training and monitoring	N Y Y Y N N N Y Y Y	Ves Yes Yes Ves Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A N/A N/A N/A N/A As the product is to be sold in India, there is no requirement for	N/A
PL-2 System security plan PL-4 Rules of behavior PL-7 Security concept of operations PL-8 Information security architecture PM-1 Information security program plan PM-9 Risk management strategy PM-12 Insider threat program PM-14 Testing, training and monitoring	N Y Y Y N N N Y Y Y	Ves Yes Yes Ves Yes Yes Yes Yes Yes	N/A N/A Hospitals doesn't require security concept of operations N/A N/A N/A N/A N/A As the product is to be sold in India, there is no requirement for	N/A N/A N/A N/A N/A N/A N/A N/A Security planning and information security program plan are shared responsibilities: (1) Stryker general: SYK has established QMS procedures and trainings for security and safety to be considered during the design&development and post market surveiliance of any SW driven Medical Device from SYK. These procedures include the specification of roles & responsibilities. (2) Application specific security planning: The PSSA, the security planning: The PSSA, the security architecture and the PS risk analysis define application specific security controls which shall be implemented in the application and considered in accompanying material eg service manual) (3) Customer specific provisions: The SOM establishes application specific security controls and guidance to be considered by the HDO for his security program planning purposes SOM D0010201115 - 35. System Security Context and Intended Environment SOM D001020115 - 35. System Security Program Integration N/A Post market Security monitoring to be conducted as per "D00000003113 - Product Security Post Market Management".

Doc Number: D000003422 Name: Product security standard assessment Revision: AB

Controls (click control name for details)	Assessment Required? Y = Control must be assessed; Number(s) refers to control enhancement(s) that must be assessed	Include?	Justification if not using NIST control and applicable control enhancement(s)/ Clarification notes	Traceability Reference
				The Corporate QMS product security policy and procedures define security roles and responsibilities which build the foundation for hiring, training, etc. for personal involved in product security
PS-1 Personnel security policy and procedures	Y	Yes	N/A	activities D001020037 - Penetration testing
RA-5 Vulnerability scanning	Y	Yes	N/A	Protocol
SA-1 System and services acquisition policy and procedures	Y	Yes	N/A	All the details related to Software SOUP document SOUP Admin D001020054; SOUP Tablet D001020055; SOUP Nurse station application D001020056. "D0000061606 - Security and privacy in
SA-3 System development life cycle	V	Yes	N/A	design controls" defines requirements and guidance for product development to establish product security and privacy by design (D0000061607) in medical devices and/or products that are software or contain software
				As Nurse Station application using 3rd party libraries, the acquisition has to be
SA-4 Acquisition process SA-5 Information system documentation	Y	Yes	N/A	mentioned in the SRS. SOUP Admin D001020054; SOUP Tablet D001020055; SOUP Nurse station application D001020056, IPU 001-02-1- 13-00-00 and Security Operations Manual (D001020115) are user documents which enable the HDD to supplement their information system documents with characteristic system documents with characteristic system documentation.
				D0000061606 - Security and privacy in design controls D0000061607 - Privacy by design
SA-8 Security engineering principles	N 	Yes	N/A	Defines security and privacy principles Currently, CAPTCHA is used for Second
SA-9 External information system services SA-10 Developer configuration management	Y N	Yes	N/A	Factor Authentication. D001020020: Configuration management in Software Development plan
				"D0000061606 - Security and privacy in design controls" defines security testing
SA-11 Developer security testing and evaluation	N N	Yes No	N/A The complete product and its purpose in hospital environment	requirements and practices
SA-12 Supply chain protection	N		doesnt need any kind of supply chain protection.	All controls which need to be considered by the HDO in order to ensure CIA are defined in the Security Operations Manual (D001020115) - Section 09. Trustworthiness- CIA Triad
SA-13 Trustworthiness	N	Yes	N/A Criticality analysis, as a part of supply chain risk management doesn't apply for this product and its usage in this hospital	& Their Responsibilities
SA-14 Criticality analysis	N	No	environment Stryker devices follow secure SDLC process. System & wireless-AP	N/A
SA-15 Development process, standards and tools	N	No	as per HDOs policies.	N/A
SA-16 Developer-provided training	N	No	All kinds of manuals provided for HDO to understand the system. No seperate training is needed from developer perspective.	N/A SOM D001020115 - Section 3.5 System Security Context and Intended
SA-17 Developer security architecture and design	N	Yes	Tablet is enclosed, no scope of tampering. System is in HDOs scope	Environment
SA-18 Tamper resistance and detection	N	No	and tamper resistance & detection as per HDO policies. This product is not national/economic security interest. Hence no	N/A
SA-21 Developer screening	N	No	need for developer screening.	N/A
SC-1 System and communications protection policy and procedures	Y	Yes	N/A	Refer to HDO IT policy for communication with internal information system, SRS for Protection of communication channel of the system
SC-7 Boundary protection	Y	No	Hospitals are not required to create DMZ or virtual network to operate the system	N/A
SC-8 Transmission confidentiality and integrity	N	Yes	N/A	D001020115: SOM -Section 11.Transmission confidentiality and integrity SOM: D001020115 - Section 22.
SC-12 Cryptographic key establishment and management	Y	Yes	Use of Wifi Security WPD-2 PSK and above for wifi access	Cryptographic Protection & Management, handshaking mechasim to use wifi SOM: D001020115 - Section 22.
SC-13 Cryptographic protection	Y	Yes	Use of Wifi Security WPD-2 PSK and above for wifi access	Cryptographic Protection & Management, handshaking mechasim to use wifi Tablet SDD:
SC-17 Public key infrastructure certificates	N	Yes		SRS Number : 5.2.4.2 (a) IOT Provisioning
SC-25 Thin nodes SC-26 Honeypots	N N	No No	Hospital doesn't need any kind of thin nodes for this product Hospital doesn't need any kind of honeypots for this product	N/A N/A
SC-28 Protection of information at rest	N	No	Sensitive data at rest is not present in the system to safeguard/protect. No group of systems required for this product to follow diversified	N/A
SC-29 Heterogeneity	N	No	practices. Techniques for concealment and misdirection is not required for	N/A
SC-30 Concealment and misdirection	N	No	this product in hospital environment. Only single secured cloud communication channel exists (IOT	N/A
SC-31 Covert channel analysis	N N	No	provisioning) and no chance of covert channels for this product Modification of s/w can only be performed by service person with	N/A
SC-34 Non-modifiable executable programs SC-35 Honey clients	N N	No No	admin access Hospital doesn't need any kind of honeyclients for this product	N/A N/A
SC-37 Out-of-band channels SC-40 Wireless link protection	N N	No No	No possibility of creating out-of-band channels as IOT device provisioning is enabled Wifi-AP is HDOs scope.	N/A N/A
SC-40 wireless link protection SC-41 Port and I/O device access	N N	No	No port & I/O devices access enabled for the components in this product	N/A
SC-42 Sensor capability and data SC-43 Usage restrictions	N N	No No	Not possible as tablet is enclosed and access restricted Not possible as tablet is enclosed and access restricted	N/A N/A
oo to oaage read redona			Hospital doesn't need any kind of detonation chambers for this	
SC-44 Detonation chambers	N	No	product	N/A



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Controls (click control name for details)	Assessment Required? Y = Control must be assessed; Number(s) refers to control enhancement(s) that must be assessed	Include?	Justification if not using NIST control and applicable control enhancement(s)/ Clarification notes	Traceability Reference
SI-2 Flaw remediation	v	Yes		12. System and information integrity 13. Malicious code protection
SI-2 Haw Telliculation	•	103		14. Information system monitoring
SI-3 Malicious code protection	Y	Yes		15. Information handling and retention
·				17. Security Alerts, Advisories, and Directives
SI-4 Information system monitoring	Y	Yes		18. Flaw remediation & Vulnerability
				Management
SI-5 Security alerts, advisories, and directives	Y	Yes		describes any controls which may assist
SI-6 Security functionality verification	N	No	No such features enabled in the components for this product.	the HDO to keep its system integrity
SI-7 Software and information integrity	N	No	NS app is a web app, hence no s/w integrity check required	(e.g. backup, malware protection, etc.)
SI-8 Spam protection	N	No	Newly spam protection not required for this product in hospital environment. Existing HDO policies handles this.	Incident management for the Nurse station application (Once it is on the
SI-10 Information input validation	N	No	No input receiving devices exists in this product	market) shall be handled as established
SI-11 Error handling	N	Yes		with the Corporate procedure
SI-12 Information handling and retention	Y	Yes		"D0000003113 - Product Security Post Market Management".
			Information processing not happening locally and getting received through web interface. Other factors (Network etc.,) are out-of-	SI-11 SRS ITEM: D001020097 -2.1.7.1.1
SI-15 Information output filtering	N	No	scope	Something went wrong with API
				operation try again / contact API admin. D001020023-2.1.4.1.1 Something went wrong with API operation try again / contact API admin.
SI-17 Fail-safe procedures	N	Yes		SI-15: Complaint Handelling Procedure



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PRODUCT SECURITY STANDARD ASSESSMENT - Privacy Controls Assessment SGTC-NPD-000-02 Product/Entity: bed frame and under the bed's mattress. The device can provide patient weight, turn indication and share information

Note: Privacy filtering questions have been answered No. PbD assessment not required.

Instructions for this worksheet

- Institutions for institutions of institutions
- 3. Clarification notes may be added to explain the method or extent to which the item will be incorporated.

 4. Once a selected control is added to the software requirements or project requirements, update the Traceability Reference field with traceability information (such as the number of the SRS or other document).

Privacy by Design Families and Sub-Elements	PbD Controls (click to read full text of related baseline requirement)	Include?	Justification if not using PbD Control Baseline Requirements / Clarification notes	Traceability Reference
I. Authority & Purpose	related baseline requirement)		Requirements / Clarification notes	
. Authority & Ful pose	1.1.1 Authority to collect in GDPR	No	N/A - Not Assessed because no Privacy impact.	
	1.1.2 Authority to collect in HIPAA	No	N/A - Not Assessed because no Privacy impact.	
1 Authority to collect	1.1.3 Authority to collect in		.,,,	
	architectural diagrams	No	N/A - Not Assessed because no Privacy impact.	
	1.2.1 Purpose specification in		,	
an a :a ::	architectural diagrams	No	N/A - Not Assessed because no Privacy impact.	
.2 Purpose Specification	1.2.2 Purpose limitation	No	N/A - Not Assessed because no Privacy impact.	
	1.2.3 Purpose definition in SOM	No	N/A - Not Assessed because no Privacy impact.	
2. Accountability, Audit, Risk Management				
.2 Privacy Impact & Risk Assessment				
.2 I I I Vacy Impact & Risk rissessment		No	N/A - Not Assessed because no Privacy impact.	
	2.7.1 Data minimization	Yes	User needs and other specs documents (like SRS) document the	application shall allow to assign and
2.7 Privacy Enhanced System design & Development	2.7.2 Pseudonymization	No	N/A - Not Assessed because no Privacy impact.	
	2.7.3 Anonymization	Yes	Process of patient data anonymization	application shall allow to assign and
	2.7.4 Encryption	No	N/A - Not Assessed because no Privacy impact.	
. Data Quality & Integrity	3.1.1 Data Quality Mechanism	No	N/A - Not Assessed because no Privacy impact.	
.1 Data Quality	3.1.2 Data integrity in the SOM	No	N/A - Not Assessed because no Privacy impact.	+
	3.2.1 Additional Data Processing	NO	N/A - Not Assessed because no i rivacy impact	
3.2 Data Integrity & Data Integrity Board	Functions for Integrity	No	N/A - Not Assessed because no Privacy impact.	
I. Data Minimization & Retention				
.1 Minimization of personally identifiable information	N/A	This sub-elen	ent is product-related, but is covered by overlapping requirements in	n sub-element 1.2.
	4.2.1 Enabling deletion of data	No	N/A - Not Assessed because no Privacy impact.	
.2 Data retention and disposal	4.2.2 Time Stamp Identification	No	N/A - Not Assessed because no Privacy impact.	
·	4.2.3 Data Disposal in SOM	No	N/A - Not Assessed because no Privacy impact.	
1.3 Minimization of PII used in Testing, Training and IP	4.3.1 Use of Dummy Data for Testing	No	N/A - Not Assessed because no Privacy impact.	
5. Individual Participation & Redress				
5.1 Consent	5.1.1 Consent if Controller	No	N/A - Not Assessed because no Privacy impact.	
.1 Consent	5.1.2 Consent if Processor	No	N/A - Not Assessed because no Privacy impact.	
2 Individual Access	5.2.1 Functionality for Individual Data			
.2 Individual Access	Access Requests	No	N/A - Not Assessed because no Privacy impact.	
.3 Redress	5.3.1 Functionality for Individual Data			
.3 Redress	Activity Requests	No	N/A - Not Assessed because no Privacy impact.	
. Security				
.1 Inventory of Personally Identifiable Information	N/A	This sub-elen	ent is product-related, but is covered by overlapping requirements in	n sub-element 1.2.
Transparency		1		
.1 Privacy Notice	7.1.1 Transparency if Controller	No	N/A - Not Assessed because no Privacy impact.	
B. Use Limitation				
8.1 Internal Use	8.1.1 Internal Use Policies	No	N/A - Not Assessed because no Privacy impact.	

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PRODUCT SECURITY STANDARD ASSESSMENT - Logic Tables

Note: The table below defines the logic for the security portion of the Controls Assessment, but not the logic for privacy, ALL items in the Controls Assessment are required to be assessed if either of the privacy-related questions on the Capabilities Assessment is answered Yes.

SELECTED	POTENTIAL	IMPACT	LEVEL
Low			

LOGIC CHART:	S	S		S	SS		S	S	S S	S	S S	S	SS	Potentially		Low								COMPINED
LOGIC CHART: CONTROL CODE AND DESCRIPTION	CAPA	BILITY	FILTER TA	ABLE	x = c	ontrol ann	lies for capab	ility: S = can	ability SEL	ECTED and th	hus contro	ol is in scone	e	In Scope		POTENTIAL-I	MPACT-BASED	CONTROL DETERMINA	ATION	IMPACT-BASED	CONTROL ENHANC	EMENTS		COMBINED FINAL
	ALOF	AUDT											TXCF TXIG	(impact-level agno	ostic)			In Scope for Low	_	LOW	MODERATE	HIGH	ACTUAL BASED ON LEVEL	
AC-1 Access control policy and management	S		х			х			S		S			Y			Y Y	Y	AC-1				0	Y
AC-2 Account management AC-3 Access enforcement	S		x x			х		S	<u>s</u>		S	+		N N	1		Y Y Y Y	Y	AC-2 AC-3		(1) (2) (3) (4)	(1) (2) (3) (4) (5) (11) (12) (13)	0	Y N
AC-5 Separation of duties			x x						+	+	_	+		N	1	N	YY	N	AC-5				0	N N
AC-6 Least Privilege			x x											N	1	N	Y Y	N	AC-6		(1) (2) (5) (9) (10)	(1) (2) (3) (5) (9) (10)	0	N
AC-7 Unsuccessful logon attempts	S		х	-				S	S					Y	1	Y	Y Y	Y	AC-7				0	Y
AC-8 System use notification AC-11 Session lock	S			+	S				+	+	_	+		Y	1	Y N	Y Y Y Y	Y N	AC-8 AC-11		(1)	(1)	0	Y N
AC-12 Session termination	S											+ +		Y	İ		YY	N	AC-12		(1)	(1)	0	N
AC-14 Permitted actions without identification or authentication						х			S					Y	1		Y Y	Y	AC-14				0	Y
AC-17 Remote access			X	S					S			+		Y	-	Y	Y Y	Y	AC-17		(1) (2) (3) (4)	(1) (2) (3) (4)	0	Y
AC-18 Wireless access AC-19 Access control for mobile devices			x x					S	<u> </u>		S	+ +		Y	1	Y	Y Y Y Y	Y	AC-18 AC-19		(1)	(1) (4) (5)	0	Y V
AC-21 Information sharing		S	x		S									Y	1	N	YY	N	AC-21		(=)	(*)	0	N
AC-23 Data mining protection		S	х		S									Y		N	N N	N	AC-23				0	N
AC-24 Access control decisions AT-1 Security awareness and training policy and procedures	S		х	+	S				_		S	+		Y	1	N Y	N N Y Y	N Y	AC-24 AT-1				0	N Y
AT-2 Security awareness training poncy and procedures				+	3				_		S			Y	1	Y	YY	Y	AT-1		(2)	(2)	0	Y
AT-3 Security training											S			Y		Y	Y Y	Y	AT-3		(-)		0	Y
AU-1 Audit and accountability policy and procedures		S						\perp						Y	1	Y	Y Y	Y	AU-1				0	Y
AU-2 Audit events AU-3 Content of audit records		S			S			S	SS					Y	1	-	Y Y Y Y	Y	AU-2 AU-3		(3)	(3)	0	Y V
AU-4 Audit storage capacity		S			3									Y	t	Y	YYY	Y	AU-3 AU-4		(1)	(1)(2)	0	Y Y
AU-5 Response to audit processing failures		S												Y	1	Y	Y Y	Y	AU-5			(1) (2)	0	Y
AU-6 Audit review, analysis and reporting		S												Y	1	Y	Y Y	Y	AU-6		(1) (3)	(1) (3) (5) (6)	0	Y
AU-7 Audit reduction and report generation AU-8 Time stamps		S								+++		+		Y	1	N Y	Y Y Y Y	N Y	AU-7 AU-8		(1)	(1)	0	N Y
AU-9 Protection of audit information		S			S S									Y	i	Y	YY	Y	AU-8 AU-9		(4)	(2) (3) (4)	0	Y
AU-10 Non-repudiation		S						S	S					Y		N	N Y	N	AU-10				0	N
AU-11 Audit record retention		S			S									Y		Y	Y Y	Y	AU-11				0	Y
AU-12 Audit generation AU-13 Monitoring for information disclosure		S		+					_	+ +	_	+		Y	1	Y N	Y Y N N	Y N	AU-12 AU-13			(1) (3)	0	Y N
AU-14 Session audit		S										1 1		Y	t	N	N N	N	AU-14				0	N
AU-15 Alternate audit capacity		S												Y		N	N N	N	AU-15				0	N
AU-16 Cross-organizational auditing		S							-			+		Y	1	N Y	N N Y Y	N Y	AU-16				0	N
CA-7 Continuous monitoring CM-1 Configuration management policy and procedures			x		S			S	S					Y	1	Y	Y Y Y Y	Y	CA-7 CM-1		(1)	(1)	0	Y V
CM-2 Baseline configuration			x		S									Y			YY	Y	CM-2		(1) (3) (7)	(1) (2) (3) (7)	0	Y
CM-3 Configuration change control			х		S		S	S						Y		N	Y Y	N	CM-3		(2)	(1) (2)	0	N
CM-4 Security impact analysis CM-5 Access restrictions for change	S		X X		S							+		Y	1	Y N	Y Y Y Y	Y N	CM-4 CM-5			(1) (2) (3)	0	Y N
CM-6 Configuration settings			X		S			S			S			Y		Y	YY	Y	CM-6		(3)	(1) (2) (3)	0	Y
CM-7 Least functionality			х								S			Y		Y	Y Y	Y	CM-7		(1) (2) (4)	(1) (2) (5)	0	Y
CM-9 Configuration management plan			x	+										N	1	N	Y Y	N Y	CM-9				0	N
CP-1 Contingency planning policy and procedures CP-2 Contingency plan					S				_		S			Y		Y	Y Y Y Y	Y	CP-1 CP-2		(1) (3) (8)	(1) (2) (3) (4) (5) (8)	0	Y Y
CP-3 Contingency training					S	\rightarrow					S			Y		Y	Y Y	Y	CP-3		(7070)	(1)	0	Y
CP-4 Contingency plan testing					S									Y			Y Y	Y	CP-4		(1)	(1) (2)	0	Y
CP-6 Alternate storage site CP-7 Alternate processing site					S				S					Y	1	N N	Y Y Y Y	N N	CP-6 CP-7		(1) (3)	(1) (2) (3) (1) (2) (3) (4)	0	N N
CP-8 Telecommunications services					S									Y	l		YY	N	CP-8		(1) (2)	(1) (2) (3) (4)	0	N
CP-9 Information system backup					S									Y	1	Y	Y Y	Y	CP-9		(1)	(1) (2) (3) (5)	0	Y
CP-10 Information system recovery and reconstitution					S					+				Y	1		Y Y	Y	CP-10		(2)	(2) (4)	0	Y
CP-13 Alternative security mechanisms IA-1 Identification and authentication policy and procedures				S	S	x		S	S					Y	1		N N Y Y	N Y	CP-13 IA-1				0	N Y
IA-2 Identification and authentication (organizational users)						_ A			S					Y	İ		YY	Y	IA-1	(1) (12)	(1) (2) (3) (8) (11) (12)	(1) (2) (3) (4) (8) (9) (11) (12)	(1) (12)	Y + (1) (12)
IA-4 Identifier management	S								S					Y			Y Y	Y	IA-4				0	Y
IA-5 Authenticator management IA-7 Cryptographic module authentication				-					S S					Y	1		Y Y Y Y	Y	IA-5	(1) (11)	(1) (2) (3) (11)	(1) (2) (3) (11)	(1) (11)	Y + (1) (11)
IA-7 Cryptographic module authentication IA-8 Identification and authentication (non-organizational users)									S					Y	1		Y Y Y Y	Y	IA-7 IA-8	(1) (2) (3) (4)	(1) (2) (3) (4)	(1) (2) (3) (4)	(1) (2) (3) (4)	Y + (1) (2) (3) (4)
IA-9 Service identification and authentication				S										Y		N	N N	N	IA-9	(-) (-) (0) (1)	(-) (-) (0) (-)	(-) (-) (0) (1)	0	N
IA-10 Adaptive identification and authentication									S					Y	1		N N	N	IA-10				0	N
IA-11 Re-authentication IR-1 Incident response policy and procedures	S				S		S		S		S			Y	1	N Y	N N Y Y	N Y	IA-11 IR-1				0	N Y
IR-2 Incident response policy and procedures					S		S S				S S			Y	1		YY	Y	IR-1 IR-2			(1) (2)	0	Y
IR-3 Incident response testing					S		S							Y	1	N	Y Y	N	IR-3		(2)	(2)	0	N
IR-4 Incident handling					S		S			1 T				Y	1		Y Y	Y	IR-4		(1)	(1) (4)	0	Y
IR-5 Incident monitoring IR-6 Incident reporting					S	\rightarrow	S							Y	1	Y	Y Y Y Y	Y	IR-5 IR-6		(1)	(1)	0	Y Y
IR-7 Incident reporting					S		S				S			Y	1	Y	YY	Y	IR-6 IR-7		(1)	(1)	0	Y
IR-8 Incident response plan					S		S				S			Y	1	Y	Y Y	Y	IR-8				0	Y
IR-9 Information spillage response					S			$\perp \perp \Gamma$		+		\bot		Y	1		N N	N	IR-9				0	N
IR-10 Integrated information security analysis team MA-1 System maintenance policy and procedures				S	S					S				Y	1		N N Y Y	N Y	IR-10 MA-1				0	N Y
MA-2 Controlled maintenance				S						S				Y	İ	Y	YY	Y	MA-1 MA-2			(2)	0	Y
MA-3 Maintenance tools				S			S			S				Y	1	N	Y Y	N	MA-3		(1) (2)	(1) (2) (3)	0	N
MA-4 Nonlocal maintenance				S										Y	1		Y Y	Y	MA-4		(2)	(2) (3)	0	Y
MA-5 Maintenance personnel				S										Y	1	Y	Y Y	Y	MA-5			(1)	0	Y

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CAPABILITY SELECTIONS FROM THE CAPABILITITES ASSESSMENT PAGE

ALOF AUDT AUTH CNFS CSUP DIDT DTBK EMRG IGAU MLDP NAUT PAUT PLOK RDMP SAHD SGUD STCF TXCF TXIG

				ILITITES ASSESSMENT										
	S S		S S	EMRG IGAU MLDP NAU'			S S S S		SELECTED POTENTIAL IMPACT LEVEL Low					
LOGIC CHART:	5 5		5 5			5 5 .	3 3 3 3	Potentially	now.					COMBINED
CONTROL CODE AND DESCRIPTION	CAPABILITY F			ol applies for capability; S = EMRG IGAU MLDP NAU				In Scope	POTENTIAL-IMPACT-BASED CONTROL DETERMINAT NIST L NIST M NIST H In Scope for Low		D CONTROL ENHANO MODERATE	CEMENTS HIGH	ACTUAL BASED ON LEVEL	FINAL
MA-6 Timely maintenance	ALUF AUDI A	S S	ו אפוע ועו	EMRG IGAU MLDP NAU	I PAUI PLOK	S SAND SG	OD SICE TACE TAIC	(impact-level agnostic)	NIST L	MA-6	MODERATE	nign	0	N
MP-1 Media protection policy and procedures		S				S		Y	Y Y Y Y	MP-1			0	Y
MP-2 Media access				S	S			Y	Y Y Y Y	MP-2			0	Y
MP-4 Media		+++			S	\rightarrow	+	Y	N Y Y N	MP-4			0	N
MP-7 Media use MP-8 Media downgrading		+++			S	S	+	Y	Y Y Y Y Y N N	MP-7 MP-8	(1)	(1)	0	Y N
PE-1 Physical and environmental protection policy and procedures		+			S	-	 	Y	Y Y Y Y	PE-1			0	Y
PE-2 Physical access authorizations					S			Y	Y Y Y Y	PE-2			0	Y
PE-3 Physical access control					S			Y	Y Y Y Y	PE-3		(1)	0	Y
PE-4 Access control for transmission medium		+			S	\rightarrow	S S	Y	N Y Y N N Y Y N	PE-4			0	N N
PE-5 Access control for output devices PE-6 Monitoring physical access		+			S	\rightarrow	+++	Y V	N Y Y N Y Y Y Y	PE-5 PE-6	(1)	(1) (4)	0	N Y
PE-9 Power equipment and power cabling					S		 	Y	N Y Y N	PE-9	(1)	(1)(4)	0	N
PE-18 Location of information system components					S			Y	N N Y N	PE-18			0	N
PL-1 Security planning policy and procedures							S	Y	Y Y Y Y	PL-1			0	Y
PL-2 System security plan PL-4 Rules of behavior					S		S S	Y	Y Y Y Y Y Y Y Y	PL-2	(3)	(3)	0	Y
PL-4 Rules of benavior PL-7 Security concept of operations		x					S	Y	Y Y Y Y Y N N	PL-4 PL-7	(1)	(1)	0	Y N
PL-8 Information security architecture							s	Y	N Y Y N	PL-8			0	N
PM-1 Information security program plan						:	S	Y	Y Y Y Y	PM-1			0	Y
PM-9 RISK MANAGEMENT strategy			S				S	Y	Y Y Y Y	PM-9			0	Y
PM-12 Insider threat program							S	Y	Y Y Y Y	PM-12			0	Y
PM-14 Testing, training and monitoring PM-15 Contacts with security groups and associations							S S	Y	Y Y Y Y Y Y Y Y Y	PM-14 PM-15			0	Y Y
PM-16 Threat awareness program							s	Y	Y Y Y Y	PM-16			0	Y
PS-1 Personnel security policy and procedures							S	Y	Y Y Y Y	PS-1			0	Y
RA-5 Vulnerability scanning				x S	S			Y	Y Y Y Y	RA-5	(1) (2) (5)	(1) (2) (4) (5)	0	Y
SA-1 System and services acquisition policy and procedures		+			+	S	+	Y	Y Y Y Y	SA-1			0	Y
SA-3 System development life cycle SA-4 Acquisition PROCESS				S		S	<u> </u>	Y	Y Y Y Y Y Y Y Y Y	SA-3 SA-4	(1) (2) (9) (10)	(1) (2) (9) (10)	0	Y Y
SA-5 Information system documentation							s	Y	YYYYY	SA-5	(1) (2) (9) (10)	(1) (2) (7) (10)	0	Y
SA-8 Security engineering principles		S		S		S		Y	N Y Y N	SA-8			0	N
SA-9 External information system services						S		Y	Y Y Y Y	SA-9	(2)	(2)	0	Y
SA-10 Developer configuration management		x				S	+	Y	N Y Y N	SA-10			0	N
SA-11 Developer security testing and evaluation SA-12 Supply chain protection		S		S	+	S	+++	Y	N Y Y N N N Y N	SA-11 SA-12			0	N N
SA-13 Trustworthiness				x S		-		Y	N N N N	SA-12 SA-13			0	N
SA-14 Criticality analysis		S				S		Y	N N N N	SA-14			0	N
SA-15 Development PROCESS, standards and tools						S		Y	N N Y N	SA-15			0	N
SA-16 Developer-provided training						S S	S	Y	N N Y N N N Y N	SA-16			0	N N
SA-17 Developer security architecture and design SA-18 Tamper resistance and detection						3 S		Y	N N N N	SA-17 SA-18			0	N N
SA-21 Developer screening						S		Y	N N N N	SA-21			0	N
SC-1 System and communications protection policy and procedures						:	S S	Y	Y Y Y Y	SC-1			0	Y
SC-7 Boundary protection		+++		S		\rightarrow		Y	Y Y Y Y	SC-7	(3) (4) (5) (7)	(3) (4) (5) (7) (8) (18 (21)	0	Y
SC-8 Transmission confidentiality and integrity SC-12 Cryptographic key establishment and management		+	_	x	S	-+	S S	Y	N Y Y N Y Y Y Y	SC-8 SC-12	(1)	(1)	0	N V
SC-13 Cryptographic rotection				x			S S	Y	Y Y Y Y	SC-13		(1)	0	Y
SC-17 Public key infrastructure certificates				х			S	Y	N Y Y N	SC-17			0	N
SC-25 Thin nodes						S		Y	N N N	SC-25			0	N
SC-26 Honeypots SC-28 Protection of information at rest				x S		S	s	Y	N N N N N Y Y N	SC-26 SC-28			0	N N
SC-29 Heterogeneity				x 3		S	3	Y	N Y Y N N N N N	SC-28 SC-29			0	N N
SC-30 Concealment and misdirection				S		S		Y	N N N N	SC-30			0	N
SC-31 Covert channel analysis						S		Y	N N N N	SC-31			0	N
SC-34 Non-modifiable executable programs				S				Y	N N N	SC-34			0	N
SC-35 Honey clients SC-37 Out-of-band channels				S		S		Y	N N N N	SC-35 SC-37			0	N
SC-40 Wireless link protection				3		S		Y	N N N N N	SC-37 SC-40			0	N N
SC-41 Port and I/O device access						S		Y	N N N N	SC-41			0	N
SC-42 Sensor capability and data						S		Y	N N N N	SC-42			0	N
SC-43 Usage restrictions						S		Y	N N N N	SC-43			0	N
SC-44 Detonation chambers				S				Y	N N N N Y Y Y Y	SC-44			0	N
SI-1 System and information integrity policy and procedures SI-2 Flaw remediation			S	x S			S S	Y	Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y	SI-1 SI-2	(2)	(1) (2)	0	Y V
SI-3 Malicious code protection				x S			s s		Y Y Y Y	SI-3	(1) (2)	(1) (2)	0	Y
SI-4 Information system monitoring				S			S	Y	Y Y Y Y	SI-4	(2) (4) (5)	(2) (4) (5)	0	Y
SI-5 Security alerts, advisories, and directives							s	Y	Y Y Y Y	SI-5		(1)	0	Y
SI-6 Security functionality VERIFICATION							S	Y	N N Y N	SI-6			0	N
SI-7 Software and information integrity		+		x S			S	Y	N Y Y N	SI-7	(1) (7)	(1) (2) (5) (7) (14)	0	N N
SI-8 Spam protection SI-10 Information input validation		+++		x			S S	Y	N Y Y N N Y Y N	SI-8 SI-10	(1) (2)	(1) (2)	0	N N
SI-10 Information input validation SI-11 Error handling		S					S	Y	N Y Y N	SI-10 SI-11			0	N N
SI-12 Information handling and retention							s	Y	Y Y Y Y	SI-12			0	Y
SI-15 Information output filtering				S				Y	N N N	SI-15			0	N
SI-17 Fail-safe procedures							S	Y	N N N N	SI-17			0	N



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REFERENCE FOR POTENTIAL IMPACT LEVEL SELECTION

From FIPS PUB 199:

SC information type = {(confidentiality, impact), (integrity, impact), (availability, impact)},

The potential impact is LOW if-

- The loss of confidentiality, integrity, or availability could be expected to have a limited adverse effect on organizational operations, organizational assets, or individuals 2 AMPLIFICATION: A limited adverse effect means that, for example, the loss of confidentiality, integrity, or availability might: (i) cause a degradation in mission capability to an extent and duration that the organization is able to perform its primary functions, but the effectiveness of the functions is noticeably reduced; (ii) result in minor damage to organizational assets; (iii) result in minor financial loss; or (iv) result in minor harm to individuals.

The potential impact is MODERATE if—

- The loss of confidentiality, integrity, or availability could be expected to have a serious adverse effect on organizational operations, organizational assets, or individuals. AMPLIFICATION: A serious adverse effect means that, for example, the loss of confidentiality, integrity, or availability might: (i) cause a significant degradation in mission capability to an extent and duration that the organization is able to perform its primary functions, but the effectiveness of the functions is significantly reduced; (ii) result in significant mange to organizational assets; (iii) result in significant financial loss; or (iv) result in significant harm to individuals that does not involve loss of life or serious life threatening injuries.

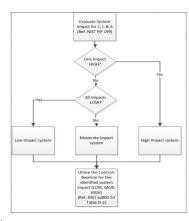
The potential impact is HIGH if-

- The loss of confidentiality, integrity, or availability could be expected to have a severe or catastrophic adverse effect on organizational operations, organizational assets, or individuals.

AMPLIFICATION: A severe or catastrophic adverse effect means that, for example, the loss of confidentiality, integrity, or availability might: (i) cause a severe degradation in or loss of mission capability to an extent and duration that the organization is not able to perform one or more of its primary functions; (ii) result in major damage to organizational assets; (iii) result in major financial loss; or (iv) result in severe or catastrophic harm to individuals involving of life or serious life threatening injuries.

A low-impact system is an information system in which all three of the security objectives are low.

A moderate-impact system is an information system in which at least one of the security objectives is moderate and no security objective is greater than moderate. A high-impact system is an information system in which at least one security objective is high.





PRODUCT SECUR	ITY STANDARD ASSESSMENT - Capability Explanations and MDS2 References			
Capability	Explanation from AAMI/IEC TIR80001-2-8:2016	Related MDS2 Qu	iestions	NIST Security Control related to MDS2 Question
AUTOMATIC LOGOFF (ALOF)	Requirement goal: Reduce the RISK of unauthorized access to HEALTH DATA from an unattended workspot. Prevent missues by other users if a system or workspot is left till for a period of time. User need: Unauthorized users are not able to access HEALTH DATA at an unattended workspot. Authorized users are not able to access HEALTH DATA at an unattended workspot. HEALTH DATA when an authorized users left the workspot without logging off or locking the display or room.	ALOF-1	Can the device be configured to force reauthorization of logged-in user(s) after a predetermined length of inactivity (e.g., auto-logoff, session lock, password protected screen saver)?	AC-12
LUGUFF (ALUF)	Automatic logoff needs to include a clearing of HEALTH DATA from all displays as appropriate. The local authorized IT administrator needs to be able to disable the function and set the expiration time (including screen savery). A screen saver with short inactivity time or manually enabled by a shortcut key might be an additional feature. This HEALTH DATA display clearing could be invoked when no key is pressed for some short period (e.g. 15 to several minutes). This would not log out the user but would reduce IRSK of cassal viewing of information. It is desirable that clinical users should not lose uncommitted work due to automatic logoff. Consider detailing characteristics under ALOF that distinguish between (a) logoff and (b) screen locking with resumption of session.	ALOF-2	Is the length of inactivity time before auto-logoff/screen lock user or administrator configurable?	AC-11
	sadniguan overeva (u) rogon unu (u) seeven ovening min resumption or session.	AUDT-1	Can the medical device create additional audit logs or reports beyond standard operating system logs?	AU-1
		AUDT-1.1	Does the audit log record a USER ID?	
		AUDT-1.2 AUDT-2	Does other personally identifiable information exist in the audit trail? Are events recorded in an audit log? If yes, indicate which of the following events are recorded in the audit	AU-2 AU-2
		AUDT-2.1	log: Successful login/logout attempts?	AU-2
		AUDT-2.2	Unsuccessful login/logout attempts?	AU-2
		AUDT-2.3 AUDT-2.4	Modification of user privileges? Creation/modification/deletion of users?	AU-2 AU-2
		AUDT-2.5	Presentation of clinical or PII data (e.g. display, print)?	AU-2
	Requirement goal: Define harmonized approach towards reliably auditing who is doing what with HEALTH DATA, allowing HDO IT to monitor this using public	AUDT-2.6		AU-2
	frameworks, standards and technology. Our industry agreed upon and HDO IT strongly prefers Integrating the Healthcare Enterprise (IHE) audit trail profile support.	AUDT-2.7 AUDT-2.8	2-3-2	AU-2 AU-2
	Audit goal (from IHE): To allow a security officer in an institution to audit activities, to assess compliance with a secure domain's policies, to detect instances of non-compliant behaviour, and to facilitate detection of improper creation, access, modification and deletion of Protected Health	AUDT-2.8.1	Remote or on-site support?	AU-2
AUDIT CONTROLS	Information (PHI). User need:	AUDT-2.8.2 AUDT-2.9		AU-2 AU-2
(AUDT) Capability to red deletion. Support for use to a separate, HI	Capability to record and examine system activity by creating audit trails on a device to track system and HEALTH DATA access, modification, or deletion.	AUDT-2.9 AUDT-2.10		AU-2
	Support for use either as a stand-alone repository (logging audit files in its own file system) or, when configured as such, will send logged information to a separate, HDO-managed central repository.	AUDT-2.11 AUDT-3		AU-2 AU-2
	Audit creation and maintenance supported by appropriate audit review tools. Securing of audit data as appropriate (especially if they contain personal data themselves).	AUDT-3 AUDT-4		AU-2 AU-2
	Audit data that cannot be edited or deleted. Audit data likely contains personal data and/or HEALTH DATA and all processing (e.g. access, storage and transfer) should have appropriate controls.	AUDT-4.1	Does the audit log record date/time?	AU-2
		AUDT-4.1.1 AUDT-5	Can date and time be synchronized by Network Time Protocol (NTP) or equivalent time source? Can audit log content be exported?	AU-2 AU-2
		AUDT-5.1	Via physical media?	NO-2
		AUDT-5.2	Via IHE Audit Trail and Node Authentication (ATNA) profile to SIEM?	
		AUDT-5.3 AUDT-5.4	Via Other communications (e.g., external service device, mobile applications)? Are audit logs encrypted in transit or on storage media?	
		AUDT-6	Can audit logs be monitored/reviewed by owner/operator?	
		AUDT-7 AUDT-7.1	Are audit logs protected from modification? Are audit logs protected from access?	AU-2
		AUDT-8	Can audit logs be analyzed by the device?	AU-2
	Requirement goal: Following the principle of data minimization, provide control of access to HEALTH DATA and functions only as necessary to perform the tasks required by the HOO consistent with the INTENDED USE.	AUTH-1	Does the device prevent access to unauthorized users through user login requirements or other mechanism?	IA-2
	User need: Avoiding unauthorized access to data and functions in order to (1) preserve system and data confidentiality, integrity and availability and (2) remain within permitted uses of data and systems.	AUTH-1.1	Can the device be configured to use federated credentials management of users for authorization (e.g., LDAP, OAuth)?	IA-2
	As defined by HDO IT policy and based on the authenticated individual user's identification, the authorization capability allows each user to only access approved data and only perform approved functions on the device.	AUTH-1.2	Can the customer push group policies to the device (e.g., Active Directory)?	IA-2
AUTHORIZATION	Authorized users include HDO and service staff as defined by that policy. • MEDICAL DEVICES typically support a permissions-based system providing access to system functions and data appropriate to the role(s) of the	AUTH-1.3	Are any special groups, organizational units, or group policies required?	IA-2
(AUTH)	individual in the HDO (role-based access control, RBAC), for example, OPEATONG can perform their assigned tasks using all appropriate device functions (e.g. monitor or scan patients). Quality staff (e.g. medical physicist) can engage in all appropriate quality and assurance testing activities.	AUTH-2	Can users be assigned different privilege levels based on 'role' (e.g., user, administrator, and/or service, etc.)?	IA-2
	Service staff can access the system in a manner that supports their preventive maintenance, problem investigation, and problem elimination activities. Authorization permits the RISK to effectively deliver healthcare while (1) maintaining system and data security and (2) following the principle of	AUTH-3	Can the device owner/operator grant themselves unrestricted administrative privileges (e.g., access operating system or application via local root or administrator account)?	IA-2
	appropriate data access minimization. Authorization can be managed locally or enterprisewide (e.g. via centralized directory). Where NTENDED USE does not permit the time necessary for logging onto and off of a device (e.g. high-throughput use), the local IT Policy can	AUTH-4	Does the device authorize or control all API access requests? Does the device run in a restricted access mode, or 'kiosk mode', by default?	IA-2
	permit reduced authorization controls presuming adequacy of controlled and restricted physical access. Requirement goal:	AUIN-5		
CONFIGURATION OF SECURITY FEATURES (CNFS)	To allow the HDO to determine how to utilize the product SECURITY CAPABILITIES to meet their needs for policy and/or workflow. User need: The local authorized IT administrator needs to be able to select the use of the product SECURITY CAPABILITIES or not to use the product SECURITY CAPABILITIES. CAPABILITIES. This can include aspects of privilege management interacting with SECURITY CAPABILITY control.	N/A		
		CSUP-1	Does the device contain any software or firmware which may require security updates during its operational life, either from the device manufacturer or from a third-party manufacturer of the software/firmware? If no, answer "NA" to questions in this section.	
		CSUP-2	Does the device contain an Operating System? If yes, complete 2.1-2.4. Does the device documentation provide instructions for owner/operator installation of patches or	
		CSUP-2.1 CSUP-2.2	software undates? Does the device require vendor or vendor-authorized service to install patches or software updates?	
		CSUP-2.2 CSUP-2.3	Does the device have the capability to receive remote installation of patches or software updates?	
		CSUP-2.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	
		CSUP-3	Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4. Does the device documentation provide instructions for owner/operator installation of patches or	
		CSUP-3.1 CSUP-3.2	Software updates? Does the device require vendor or vendor-authorized service to install patches or software updates?	
		CSUP-3.2 CSUP-3.3	Does the device have the capability to receive remote installation of patches or software updates?	
		CSUP-3.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	
		CSUP-4	Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4. Does the device documentation provide instructions for owner/operator installation of patches or	
	Requirement goal:	CSUP-4.1 CSUP-4.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	
	Create a unified way of working. Installation / Upgrade of product security patches by on-site service staff, remote service staff, and possibly authorized HDO staff (downloadable patches). User need:	CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	
CYBER SECURITY	User need: Installation of third party security patches on medical products as soon as possible in accordance with regulations requiring: • Highest priority is given to patches that address high-RISK vulnerabilities as judged by objective, authoritative, documented, MDM vulnerability	CSUP-4.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	
PRODUCT	RISK EVALUATION.	CSUP-5	Does the device contain Non-Operating System commercial off-the-shelf components? If yes, complete 5.1-5.4.	
UPGRADES (CSUP)	 The medical product vendor and the healthcare provider are required to assure continued safe and effective clinical functionality of their products. Understanding of local MEDICAL DEVICE regulation (in general, MEDICAL) DEVICES should not be natched or modified without exolicit written instructions from the MDM. 	CSUP-5.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	
	should not be patched or modified without explicit written instructions from the MDM). *Adequate testing has to be done to discover any unanticipated side effects of the patch on the medical product (performance or functionality) that might endanger a PATIENT.	CSUP-5.2 CSUP-5.3	Does the device require vendor or vendor-authorized service to install patches or software updates? Does the device have the capability to receive remote installation of patches or software updates?	
	might endanger a PATIENT. User, especially HDO IT staff and HDO service, requires proactive information on assessed/validated patches.	CSUP-5.3 CSUP-5.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g.,	
		CSUP-6	Microsoft) to be installed without approval from the manufacturer? Does the device contain other software components (e.g., asset management software, license management)? If you also provided details or reference in other and complete 6.1.6.4.	
		CSUP-6.1	management)? If yes, please provide details or reference in notes and complete 6.1-6.4. Does the device documentation provide instructions for owner/operator installation of patches or conference undetec?	
		CSUP-6.2	software updates? Does the device require vendor or vendor-authorized service to install patches or software updates?	
		CSUP-6.3	Does the device have the capability to receive remote installation of patches or software updates? Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g.,	
		CSUP-6.4	Microsoft) to be installed without approval from the manufacturer?	
		CSUP-7 CSUP-8	Does the manufacturer notify the customer when updates are approved for installation? Does the device perform automatic installation of software updates?	
		CSUP-9	Does the manufacturer have an approved list of third-party software that can be installed on the device?	
		CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	
		CSUP-10.1	Does the system have mechanism in place to prevent installation of unapproved software?	
		CSUP-11	Does the manufacturer have a process in place to assess device vulnerabilities and updates?	

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Capability	Explanation from AAMI/IEC TIR80001-2-8:2016	Related MDS2 Qu		NIST Security Control related to MDS2 Question
		CSUP-11.1 CSUP-11.2	Does the manufacturer provide customers with review and approval status of updates? Is there an update review cycle for the device?	
	Requirement goal:	DIDT-1	is there an update review cycle for the device? Does the device provide an integral capability to de-identify personally identifiable information?	
HEALTH DATA DE-	Ability of equipment (application software or additional tooling) to directly remove information that allows identification of patient. Data scrubbing prior to shipping back to factory; architecting to allow remote service without HEALTH DATA access/exposure; in-factory quarantine,	DID1-1	Does the device provide an integral capability to desidentify personally identifiable information:	
(DIDT)	labelling, and training. User need:	DIDT-1.1	Does the device support de-identification profiles that comply with the DICOM standard for de- identification?	
	Clinical user, service engineers and marketing need to be able to de-identify HEALTH DATA for various purposes not requiring PATIENT identity.		Does the device maintain long term primary storage of personally identifiable information / patient	
	Requirement goal:	DTBK-1	information (e.g. PACS)? Does the device have a "factory reset" function to restore the original device settings as provided by the	
ATA BACKUP AND	Assure that the healthcare provider can continue business after damage or destruction of data, hardware, or software. User need:	DTBK-2 DTBK-3	manufacturer? Does the device have an integral data backup capability to removable media?	CP-9 CP-9
DISASTER ECOVERY (DTBK)	Reasonable assurance that persistent system settings and persistent HEALTH DATA stored on products can be restored after a system failure or compromise so that business can be continued.	DTBK-4	Does the device have an integral data backup capability to remote storage?	Gr-9
	NOTE This requirement might not be appropriate for smaller, low-cost devices and can, in practice, rely on the ability to collect new, relevant data in the next acquisition cycle (e.g. short-duration heart rate data lost due to occasional wireless signal loss)	DTBK-5	Does the device have a backup capability for system configuration information, patch restoration, and software restoration?	
		DTBK-6	Does the device provide the capability to check the integrity and authenticity of a backup?	CP-9
EMERGENCY ACCESS (EMRG)	Requirement goal: Ensure that access to protected HEALTH DATA is possible in case of an emergency situation requiring immediate access to stored HEALTH DATA. User need: During emergency situations, the clinical user needs to be able to access HEALTH DATA without personal user id and authentication (break-glass functionality). Emergency access to to be detected, recorded and reported. Ideally including some manner of immediate notification to the system administrator or medical staff (in addition to audit record). Emergency accessed to require and record self-attented user identification as entered (without authentication). HID can solve this through procedural approach using a specific user account or function of the system. The administrator needs to be able to enable/disable any emergency functions provided by the product dependent on technical or procedural controls are required.	EMRG-1	Does the device incorporate an emergency access (i.e. "break-glass") feature?	SI-17
HEALTH DATA INTEGRITY AND	Requirement goal: Assure that HEALTH DATA has not been altered or destroyed in non-authorized manner and is from the originator. Assure integrity of HEALTH DATA.	IGAU-1	Does the device provide data integrity checking mechanisms of stored health data (e.g., hash or digital signature)?	SC-28
AUTHENTICITY (IGAU)	User need: User was the assurance that HEALTH DATA is reliable and not tampered with. Solutions are to include both fixed and also removable media.	IGAU-2	Does the device provide error/failure protection and recovery mechanisms for stored health data (e.g., RAID-5)?	SC-28
		MLDP-1	Is the device capable of hosting executable software? Does the device support the use of anti-malware software (or other anti-malware mechanism)? Provide	
		MLDP-2	details or reference in notes.	SI-3
		MLDP-2.1 MLDP-2.2	Does the device include anti-malware software by default? Does the device have anti-malware software available as an option?	CM-5 AU-6
		MLDP-2.2 MLDP-2.3	Does the device nave anti-manware software available as an option? Does the device documentation allow the owner/operator to install or update anti-malware software?	CP-10
	Requirement goal: Product supports regulatory, HDO and user needs in ensuring an effective and uniform support for the prevention, detection and removal of malware.	MLDP-2.4	Can the device owner/operator independently (re-)configure anti-malware settings?	AU-2
MALWARE	This is an essential step in a proper defence in depth approach to security. Malware application software is updated, malware pattern data files kept current and operating systems and applications are patched in a timely	MLDP-2.5	Does notification of malware detection occur in the device user interface?	
ETECTION/PROT ECTION (MLDP)	fashion. Postupdating VERIFICATION testing of device operation for both continued INTENDED USE and SAFETY is often necessary to meet regulatory quality requirements.	MLDP-2.6 MLDP-2.7	Can only manufacturer-authorized persons repair systems when malware has been detected? Are malware notifications written to a log?	
	HDOs need to detect traditional malware as well as unauthorized software that could interfere with proper operation of the device/system.	MLDP-2.8	Are there any restrictions on anti-malware (e.g., purchase, installation, configuration, scheduling)?	
	noos need to detect traditional manware as wen as disautionized software that could interied e with proper operation of the device/system.	MLDP-3	If the answer to MLDP-2 is NO, and anti-malware cannot be installed on the device, are other compensating controls in place or available?	SI-2
		MLDP-4	Does the device employ application whitelisting that restricts the software and services that are permitted to be run on the device?	SI-3
		MLDP-5	Does the device employ a host-based intrusion detection/prevention system?	SI-4
		MLDP-5.1 MLDP-5.2	Can the host-based intrusion detection/prevention system be configured by the customer? Can a host-based intrusion detection/prevention system be installed by the customer?	CM-7
	Requirement goal:	NAUT-1	Does the device provide/support any means of node authentication that assures both the sender and the recipient of data are known to each other and are authorized to receive transferred information (e.g. Web	SC-23
NODE UTHENTICATION	Authentication policies need to be flexible to adapt to local HDO IT policy. As necessary, use node authentication when communicating HEALTH DATA. User need: Capability of managing cross-machine accounts on a modality to protect HEALTH DATA access.	NAUT-2	APIs_SMTP_SMMP)? Are network access control mechanisms supported (E.g., does the device have an internal firewall, or use a network connection white list)?	SC-7
(NAUT)	Support for node authentication according to industry standards.	NAUT-2.1	Is the firewall ruleset documented and available for review?	
	To detect and prevent entity falsification (provide non-repudiation).	NAUT-3	Does the device use certificate-based network connection authentication?	
		PAUT-1	Does the device support and enforce unique IDs and passwords for all users and roles (including service	IA-2
		PAUT-1.1	accounts)? Does the device enforce authentication of unique IDs and passwords for all users and roles (including	IA-2
		PAUT-2	service accounts)? Is the device configurable to authenticate users through an external authentication service (e.g., MS Active	IA-5
	Requirement goal:	PAUT-3	Directory, NDS, LDAP, OAuth, etc.)? Is the device configurable to lock out a user after a certain number of unsuccessful logon attempts?	IA-2
	Authentication policies need to be flexible to adapt to HDO IT policy. This requirement as a logical place to require person authentication when providing access to HEALTH DATA.	PAUT-4	Are all default accounts (e.g., technician service accounts, administrator accounts) listed in the documentation?	SA-4(5)
	To control access to devices, network resources and HEALTH DATA and to generate non-repudiatable audit trails. This feature should be able to identify unambiguously and with certainty the individual who is accessing the network, device or resource.	PAUT-5	Can all passwords be changed?	
PERSON UTHENTICATION	NOTE This requirement is relaxed during "break-glass" operation. See capability "Emergency access."	PAUT-6	Is the device configurable to enforce creation of user account passwords that meet established (organization specific) complexity rules?	IA-2
(PAUT)	Capability of managing accounts on a modality to protect HEALTH DATA access. Desirable to link to personal settings/preferences.	PAUT-7	Does the device support account passwords that expire periodically?	
	Desil above to link to per solial settings) preferences. Support for stand-alone and central administration. Single sign-on and same password on all worksnots.	PAUT-8 PAUT-9	Does the device support multi-factor authentication? Does the device support single sign-on (SSO)?	IA-2
	To detect and prevent person falsification (provide non-repudiation).	PAUT-10	Can user accounts be disabled/locked on the device?	
	Role based access control (RBAC) capability desirable.			IA-2
		PAUT-11	Does the device support biometric controls?	IA-2 IA-2
		PAUT-11 PAUT-12 PAUT-13	Does the device support biometric controls? Does the device support physical tokens (e.g. badge access)? Does the device support group authentication (e.g. hospital teams)?	
		PAUT-12 PAUT-13 PAUT-14	Does the device support physical tokens (e.g. badge access)? Does the device support group authentication (e.g. hospital teams)? Does the application or device store or manage authentication credentials?	
	Requirement soal:	PAUT-12 PAUT-13 PAUT-14 PAUT-14.1	Does the device support physical tokens (e.g. badge access)? Does the device support group authentication (e.g. hospital teams)? Does the application or device store or manage authentication credentials? Are credentials stored using a secure method?	IA-2
	Requirement goal: Assure that unauthorized access does not compromise the system or data confidentiality, integrity and availability. Here non-the-the-the-the-the-the-the-the-the-the	PAUT-12 PAUT-13 PAUT-14	Does the device support physical tokens (e.g. badge access)? Does the device support group authentication (e.g. hospital teams)? Does the application or device store or manage authentication rerdentials? Are credentials stored using a secure method? Is the device software only? If yes, answer "N/A" to remaining questions in this section. Are all device on opposents maintaining personally identifiable information (other than removable media)	
	Assure that unauthorized access does not compromise the system or data confidentiality, integrity and availability. User need: Reasonable assurance that HEALTH DATA stored on products or media is and stays secure in a manner proportionate to the sensitivity and volume of	PAUT-12 PAUT-13 PAUT-14 PAUT-14.1 PLOK-1	Does the device support physical tokens (e.g. badge access)? Does the device support group authentication (e.g. hospital teams)? Does the application or device store or manage authentication credentials? Are credentials stored using a secure method? Is the device software only? If yes, answer "N/A" to remaining questions in this section. Are all device on opposents maintaining personally identifiable information (other than removable media) physically secure (i.e., cannot remove without tools)? Are all device on opposents maintaining personally identifiable information (other than removable media)	IA-2 PE- 3(4) PE- 3(4)
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PHYSICAL LOCKS (PLOK) ROADMAP FOR THIRD PARTY	Assure that unauthorized access does not compromise the system or data confidentiality, integrity and availability. User need: Reasonable assurance that HEALTH DATA stored on products or media is and stays secure in a manner proportionate to the sensitivity and volume of data records on the device. Systems are reasonably free from tampering or component removal that might compromise integrity, confidentiality or availability. Tampering (criticaling device removal) is detectable. Requirement posit INDS want an understanding of security throughout the full life cycle of a MEDICAL DEVICE. MIDM plans such that products are sustainable throughout their life cycle according internal quality systems and external regulations. Products provided with clear statement of expected life span. provided with clear statement of expected life span. software includes operating systems, database systems, report generators, medical manages processing component ests. Cassampton is the accident products are component obsolescence).	PAUT-12 PAUT-13 PAUT-14 PAUT-14.1 PLOK-1 PLOK-2 PLOK-3 PLOK-4	Does the device support plyuga altokens (e.g. badge access)? Does the device support group authentication (e.g. baspital teams)? Does the application or device store or manage authentication credentials? Are credentials stored using a secure method? Is the device software only? If yes, answer "N/A" to remaining questions in this section. Are all device components maintaining personally identifiable information (other than removable media) abrivaicilly secure (i.e., cannot remove without tools), and the second of the second personal properties of the second personal properties of the second personal properties of the second personal properties of the second personal	IA-2 PE- 3(4) PE- 3(4) PE- 3(4)
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PHYSICAL LOCKS (PLOK) ROADMAP FOR THIRD PARTY COMPONENTS IN EVICE LIFE CYCLE (RDMP)	Assure that unauthorized access does not compromise the system or data confidentiality, integrity and availability. User need: Reasonable assurance that HEALTH DATA stored on products or media is and stays secure in a manner proportionate to the sensitivity and volume of data records on the device. Systems are reasonably free from tampering or component removal that might compromise integrity, confidentiality or availability. Tampering (undufuling device removal) is detectable. Requirement goal: HOS want an understanding of security throughout the full life cycle of a MEDICAL DEVICE. MDM plans such that products are sustainable throughout their life cycle according internal quality systems and external regulations. Products provided with clear statement of expected life span. Goal is to proactively manage impact of life cycle of components throughout a product's full life cycle. This commercial off-the-shelf or 3rd party software includes operating systems, database systems, report generators, medical imaging processing components etc. (assumption is that esisting product creation processes aiready manages hardware component obsolescence). The cycle of the cycle	PAUT-12 PAUT-13 PAUT-14 PAUT-14-1 PAUT-14-1 PLOK-1 PLOK-2 PLOK-3 PLOK-4 RDMP-1 RDMP-2 RDMP-3 RDMP-3 RDMP-3 SAHD-1 SAHD-1 SAHD-3 SAHD-3 SAHD-3 SAHD-5 SAHD-5 SAHD-5 SAHD-5 SAHD-6	Does the device support plyugual tokens (e.g. hadage access)? Does the device support group authentication (e.g. hospital teams)? Does the application or device store or manage authentication credentials? Are credentials stored using a secure method? Is the device components maintaining personally identifiable information (other than removable media) and device components maintaining personally identifiable information (other than removable media) and device components maintaining personally identifiable information (other than removable media) and device components maintaining personally identifiable information (other than removable media) and device components maintaining personally identifiable information (other than removable media) and device components maintaining personally identifiable information (other than removable media) and device of the	PE-3(4) PE-3(4) PE-3(4) PE-3(4) PE-3(4) PE-3(4) PE-3(4) AC-17(2)/IA-3 SA-12(10) CM-8 AC-3 CM-7 CM-7 CM-8
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Capability	Explanation from AAMI/IEC TIR80001-2-8:2016	Related MDS2 Q	uestions	NIST Security Control related to MDS2 Question
(SAHD)	maintenance activities. HDO IT requires systems connected to their network to be secure on delivery and hardened against misuse and attacks.	SAHD-8	Are all communication ports and protocols that are not required for the intended use of the device disabled?	SA-18
	It is desirable for the user to inform the MDM of suspected security breaches and perceived weaknesses in user equipment.	SAHD-9	Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which are not required for the intended use of the device deleted/disabled?	CM-6
		SAHD-10	Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the intended use of the device deleted/disabled?	SI-2
		SAHD-11	Can the device prohibit boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?	
		SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	
		SAHD-13	Does the product documentation include information on operational network security scanning by users?	
		SAHD-14	Can the device be hardened beyond the default provided state?	
		SAHD-14.1	Are instructions available from vendor for increased hardening?	
		SHAD-15	Can the system prevent access to BIOS or other bootloaders during boot?	
		SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	
	Requirement goal: Ensure that security guidance for OPERATORS and administrators of the system is available. Separate manuals for OPERATORS and administrators	SGUD-1	Does the device include security documentation for the owner/operator?	AT-2/PL-2
SECURITY	(Including MDM sales and service) are desirable as they allow understanding of full administrative functions to be kept only by administrators. User need:	SGUD-2	Does the device have the capability, and provide instructions, for the permanent deletion of data from the device or media?	MP-6
GUIDANCE (SGUD)	OPERATOR should be clearly informed about his responsibilities and secure way of working with the system. The administrator needs information about managing, customizing and monitoring the system (i.e. access control lists, audit logs, etc.). Administrator needs clear understanding of SECURITY CAPABILITIES to allow HEALTH DATA RISK ASSESSMENT per appropriate regulatory	SGUD-3	Are all access accounts documented?	AC-6,IA-2
	requirement. Sales and service also need information about the system's SECURITY CAPABILITIES and secure way of working.	SGUD-3.1	Can the owner/operator manage password control for all accounts?	
	It is desirable for the user to know how and when to inform the MDM of suspected security breaches and perceived weaknesses in user equipment.	SGUD-4	Does the product include documentation on recommended compensating controls for the device?	
		STCF-1	Can the device encrypt data at rest?	SC-28
	Requirement goal: MDM establishes technical controls to mitigate the potential for compromise to the integrity and confidentiality of HEALTH DATA stored on products	STCF-1.1	Is all data encrypted or otherwise protected?	
HEALTH DATA	or removable media. User need:	STCF-1.2	Is the data encryption capability configured by default?	
STORAGE CONFIDENTIALITY	Reasonable assurance that HEALTH DATA stored on products or media is and stays secure. Encryption has to be considered for HEALTH DATA stored on MEDICAL DEVICES based on RISK ANALYSIS.	STCF-1.3	Are instructions available to the customer to configure encryption?	
(STCF)	For HEALTH DATA stored on removable media, encryption might protect confidentiality/integrity for clinical users but also MDM service and application engineers collecting clinical data.	STCF-2	Can the encryption keys be changed or configured?	SC-28
	A mechanism for encryption key management consistent with conventional use, service access, emergency "break-glass" access.	STCF-3	Is the data stored in a database located on the device?	
	Encryption method and strength takes into consideration the volume (extent of record collection/aggregation) and sensitivity of data.	STCF-4	Is the data stored in a database external to the device?	
	Requirement goal:	TXCF-1	Can personally identifiable information be transmitted only via a point-to-point dedicated cable?	CM-7
TRANSMISSION	Device meets local laws, regulations and standards (e.g. USA HIPAA, EU 95/46/EC derived national laws) according to HDO needs to ensure the confidentiality of transmitted HEALTH DATA.	TXCF-2	Is personally identifiable information encrypted prior to transmission via a network or removable media?	CM-7
CONFIDENTIALITY	User need:	TXCF-2.1	If data is not encrypted by default, can the customer configure encryption options?	
(TXCF)	Assurance that HEALTH DATA confidentiality is maintained during transmission between authenticated nodes. This allows transport of HEALTH DATA over relatively open networks and/or environment where strong HDO IT policies for HEALTH DATA	TXCF-3	Is personally identifiable information transmission restricted to a fixed list of network destinations?	CM-7
(1,0.7)	integrity and confidentiality are in use.	TXCF-4	Are connections limited to authenticated systems?	CM-7
	See IEC TR 80001-2-3:2012 for more information on RISK MANAGEMENT for wireless network systems.	TXCF-5	Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)?	
TRANSMISSION INTEGRITY (TXIG)	Requirement goal: Device protects the integrity of transmitted HEALTH DATA. User need: Assurance that integrity of HEALTH DATA is maintained during transmission. This allows transmission of HEALTH DATA over relatively open	TXIG-1	Does the device support any mechanism (e.g., digital signatures) intended to ensure data is not modified during transmission?	SC-8



PRODUCT SECURITY STANDARD ASSES	SSMENT - Security Controls and Guidance				
Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
AC-1 ACCESS CONTROL POLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. An access control policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the access control policy and associated access controls; and b. Reviews and updates the current: 1. Access control policy [Assignment: organization-defined frequency]; and 2. Access control procedures [Assignment: organization-defined frequency].	A.5.1.1, A.5.1.2, A.6.1.1, A.9.1.1, A.12.1.1,	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the AC family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizations risk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
AC-2 ACCOUNT MANAGEMENT	a. Identifies and selects the following types of information system accounts to support organizational missions/business functions: [Assignment: organization-defined information system account types]; b. Assigns account managers for information system accounts; c. Establishes conditions for group and role membership; d. Specifies authorized users of the information system, group and role membership, and access authorizations (Le., privileges) and other attributes (as required) for each account; e. Requires approvals by [Assignment: organization-defined personnel or roles] for requests to create information system accounts; f. Creates, enables, modifies, disables, and removes information system accounts in accordance with [Assignment: organization-defined procedures or conditions]; g. Monitors the use of information system accounts; h. Notifies account managers: l. When accounts are no longer required; 2. When users are terminated or transferred; and 3. When individual information system usage or need-to-know changes; l. Authorizes access to the information system based on: l. A valid access authorization; c. Intended system usage; and 3. Other attributes as required by the organization or associated missions/business functions; l. Reviews accounts for compliance with account management requirements [Assignment: organization-defined frequency]; and k. Establishes a process for reissuing shared/group account credentials (if deployed) when individuals are removed from the group.		could affect information system availability. Temporary and emergency accounts are accounts intended for short- term use. Organizations establish temporary accounts as a part of normal account activation procedures when then is a need for short-term accounts without the demand for immediacy in account activation. Organizations establish emergency accounts in response to crisis situations and with the need for rapid account activation. Therefore, emergency accounts activation may bypass normal account authorization processes. Emergency and temporary accounts are not to be confused with infrequently used accounts (e.g., local logon accounts used for special tasks defined by organizations or when network resources are unavailable). Such accounts remain available and are defined by organizations or when network resources are unavailable). Such accounts remain available and available and the control subject to automatic disabling or removal dates. Conditions for disabling or deactivating accounts include, for example: (1) when shared/group, emergency, or temporary accounts are no longer required, or (ii) when individual	Supplemental Guidance: Related controls: AII-2, AII-12. (5) ACOUNT MNA/AGEMENT INACTIVITY LOGUIT The organization requires that users log out when [Assignment: organization-defined time-period of expected inactivity or description of when to log out]. Supplemental Guidance: Related controls S-C23. (6) ACCOUNT MNA/AGEMENT DYNAMIC PRIVILEGE MANAGEMENT The information system implements the following dynamic privilege management capabilities: [Assignment: organization-defined list of dynamic privilege management capabilities]. Supplemental Guidance: In contrast to conventional access control approaches (e.g., service-oriented architectures) rely on run time access control decisions facilitated by dynamic privilege management. While user identities may remain relatively constant over time, user privileges may change more frequently based on ongoing mission/business requirements and operational needs of organizations. Dynamic privilege management can include, for example, the immediate revocation of privileges from users, as opposed to requiring that users terminate and restart their sessions to reflect any changes in privileges. Dynamic privilege management can also refer to mechanisms that change the privileges of users based on dynamic rules as opposed to editing specific user profiles. This type of privilege management includes, for example, automatic adjustments of privileges if users are operating out of their normal work times, or if information systems are under duress or in emergency maintenance situations. This control enhancement also includes the ancillary effects of privilege changes, for example, the potential changes to encryption keys used for communications. Dynamic privilege management can support requirements for information systems are under duress or in emergency maintenance situations. This control enhancement also includes the ancillary effects of privilege changes, for example, the potential changes to encryption keys used for communications. Dynamic privilege management can support r	None
AC-3 ACCESS ENFORCEMENT	The information system enforces approved authorizations for logical access to information and system resources in accordance with applicable access control policies.	A622, A9.12, A9.41, A9.44, A9.45, A13.11, A14.12, A14.13, A181.3	Access control policies (e.g., identity-based policies, role-based policies, control matrices, cryptography) control access between active entities or subjects (i.e., users or processes acting on behalf of users) and passive entities or objects (e.g., devices, files, records, domains) in information systems. In addition to enforcing authorized access at the information systeme level and recognizing that information systems can host many applications and services in support of organizational missions and business operations, access enforcement mechanisms can also be employed at the application and service level to provide increased information security. Related controls Ac-2, Ac-4, Ac-5, Ac-6, Ac-16, Ac-17, Ac-18, Ac-19, Ac-20, Ac-21, Ac-22, AU-9, CM-5, CM-6, CM-11, AC-3, MA-4, MA-5, PE-3.	Interiority visibility of the properties of an invalidance residence in the information system across control part (as system) and the properties of an invalidation of the provided provided and provid	None
AC-5 SEPARATION OF DUTIES	The organization: a. Separates [Assignment: organization-defined duties of individuals]; b. Documents separation of duties of individuals; and c. Defines information system access authorizations to support separation of duties.	A6.1.2	Separation of duties addresses the potential for abuse of authorized privileges and helps to reduce the risk of malevolent activity without collusion. Separation of duties includes, for example: (1) dividing mission functions and information system support functions among different individuals and/or roles; (ii) conducting information system support functions with different individuals (e.g., system management, programming, configuration management, quality assurance and testing, and network security); and (iii) ensuring security personnel administerating access control functions do not also administer audit functions. Related controls &A.O.4.6. p.B.3. p.B.4. p.S-2.		None
AC-6 LEAST PRIVILEGE	The organization employs the principle of least privilege, allowing only authorized accesses for users (or processes acting on behalf of users) which are necessary to accomplish assigned tasks in accordance with organizational missions and business functions.	A 9.1.2, A 9.2.3, A 9.4.4, A 9.4.5	Organizations employ least privilege for specific duties and information systems. The principle of least privilege is also applied to information system processes, ensuring that the processes operate at privilege levels no higher than necessary to accomplish required organizations diminisments functions. Organizations consider the creation of additional processes, roles, and information system accounts as necessary, to achieve least privilege. Organizations also apply least privilege to the development, implementation, and operation of organizational information systems. Related controls: AC-2, AC-3, AC-5, CM-6, CM-7, PL-2.	(a) LEAT PRIVILECE INITIORIZE ACCESS TO SECURITY FUNCTIONS The organization explicitly authorizes access to Assignment organization-defined security functions (deployed in hardware, software, and firmware) and security-relevant information]. Supplemental Guidance: Security functions include, for example, establishing system accounts, configuring access authorizations (i.e., permissions, privileges), setting events to be audited, and setting intrusion detection supplemental Guidance: Security functions include, for example, establishing system accounts, configuration parameters for security services, and access control lists explicitly authorized personnel include, for example, security administrators, system and network administrators, system maintenance personnel, system programmers, and other privileged sucess. Explicitly authorized personnel include, for example, security administrators, system and network administrators, system maintenance personnel, system programmers, and other privileged sucess. Explicitly authorized personnel include, for example, security administrators, system and network administrators, system and network administrators, system maintenance personnel, system programmers, and other privileged sucess. Explicitly authorized personnel include, for example, security administrators, system and network administrators, system and network access to (Ass. Acc. 19.) (2) LEAST PRIVILECE (INSTANCE) ACCESS FOR NONSECURITY FUNCTIONS The organization requires that users of information justem access control provides the same degree of assurance in the change of access authorizations for both the user and all processes acting on behalf of the user as would be provided by a change between a privileged account security and non-privileged accounts access in the security plan for the information system. (3) LEAST PRIVILECE (INSTANCE) ACCESS TO PRIVILECE (DOMMANS) The organization authorizes network access to fassignment: organization-defined privileges organization experiments and administrator of the	None

Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
C-7 NSUCCESSFUL LOGON ATTEMPTS	The information system: a. Enforces a limit of [Assignment: organization-defined number] consecutive invalid logon attempts by a user during a [Assignment: organization-defined time period]; and b. Automatically [Selection: locks the account/node for an [Assignment: organization-defined time period]; locks the account/node until released by an administrator, delays next logon prompt according to [Assignment: organization-defined delay algorithm]] when the maximum number of unsuccessful attempts is exceeded.		This control applies regardless of whether the logon occurs via a local or network connection. Due to the potential for denial of service, automatic lockouts initiated by information systems are usually temporary and automatically release after a predetermined time period established by organizations. If a delay algorithm is selected, organizations may choose to employ different algorithms for different information system components based on the capabilities of those components. Responses to unsuccessful logon attempts may be implemented at both the operating system and the application levels. Related controls: AC-2, AC-9, AC-14, IA-5.	(1) UNSUCCESSFUL LOGON ATTEMPTS AUTOMATIC ACCOUNT LOCK [Withdrawn: Incorporated into AC-7]. (2) UNSUCCESSFUL LOGON ATTEMPTS PURGE / WIPE MOBILE DEVICE The information system purges/wipes information from [Assignment: organization-defined mobile devices] based on [Assignment: organization-defined purging/wiping requirements/techniques] after [Assignment: organization-defined number] consecutive, unsuccessful device logon attempts. Supplemental Guidance: This control enhancement applies only to mobile devices for which a logon occurs (e.g., personal digital assistants, smart phones, tablets). The logon is to the mobile device, not to any one account on the device. Therefore, successful logons to any accounts on mobile devices extent the unsuccessful logon count to zero. Organizations define information to be purged/wiped carefully in order to avoid over purging/wiping which may result in devices becoming unusable. Purging/wiping may be unnecessary if the information on the device is protected with sufficiently strong encryption mechanisms. Related controls: AC-19, MP-5, MP-6, SC-13.	None
C-8 STEM USE NOTIFICATION	The information system: a. Displays to users [Assignment: organization-defined system use notification message or banner) before granting access to the system that provides privacy and security notices consistent with applicable federal laws, Executive Orders, directives, policies, regulations, standards, and guidance and states that: 1. Users are accessing a U.S. Government information system; 2. Information system usage may be monitored, recorded, and subject to audit; 3. Unauthorized use of the information system is prohibited and subject to criminal and civil penalties; and 4. Use of the information system indicates consent to monitoring and recording; b. Retains the notification message or banner on the screen until users acknowledge the usage conditions and take explicit actions to log on to or further access the information system; and c. For publicly accessible systems: 1. Displays system use information [Assignment: organization-defined conditions], before granting further access; 2. Displays references; (I any, to monitoring, recording, or auditing that are consistent with privacy accommodations for such systems that generally prohibit those activities; and 3. Includes a description of the authorized uses of the system.	A.9.4.2	System use notifications can be implemented using messages or warning banners displayed before individuals log in to information systems. System use notifications are used only for access via logon interfaces with human users and are not required when such human interfaces do not exist. Organizations consider system use notification messages (harmoners displayed in multiple languages based on specific organizational needs and the demographics of information system users. Organizations also consult with the Office of the General Counsel for legal review and approval of warning banner content. Session locks are temporary actions taken when users stop work and move away from the immediate vicinity of	None	None
C-11 SSSION LOCK	a. Prevents further access to the system by initiating a session lock after [Assignment: organization-defined time period] of inactivity or upon receiving a request from a user; and b. Retains the session lock until the user reestablishes access using established identification and authentication procedures.	A.11.2.8, A.11.2.9	information systems but do not want to log out because of the temporary nature of their absences. Session locks are implemented where session activities can be determined. This is typically at the operating system level, but can also be at the application level. Session locks are not an acceptable substitute for logging out of information systems, for example, if organizations require users to log out at the end of workdays. Related control: AC-7.	The information system conceas, via the session lock, miormation previously visione on the display with a plunicity viewable image. Sunnlemental Guidance-Public viewable images can include static or dynamic images for example natures used with screen savers photographic images solid colors clock hattery life indicator, or a blank screen with the	None
C-12 ESSION TERMINATION	The information system automatically terminates a user session after [Assignment: organization-defined conditions or trigger events requiring session disconnect].	None	access) without terminating network sessions. Session termination terminates all processes associated with a user's logical session except those processes that are specifically created by the user (i.e., session owner) to continue after the session is terminated. Conditions or trigger events requiring automatic session termination can include, for		None
C-14 ERMITTED ACTIONS WITHOUT EENTIFICATION OR AUTHENTICATION	The organization: a. Identifies [Assignment: organization-defined user actions] that can be performed on the information system without identification or authentication consistent with organizational missions; business functions; and b. Documents and provides supporting rationale in the security plan for the information system, user actions not requiring identification or authentication.	None	This control addresses situations in which organizations determine that no identification or authentication is required in organizational information systems. Organizations may allow a limited number of user actions without identification or authentication including, for example, when individuals access public websites or other publicly accessible federal information systems, when individuals use mobile phones to receive calls, or when facismiles are received. Organizations also identify actions that normally require identification or authentication but may under certain circumstances (e.g., emergencies), allow identification or authentication matchanisms to be bypassed. Such bypasses may occur, for example, via a software-readable physical switch that commands bypass of the logon functionality and is protected from accidental or unmonitored use. This control does not apply to situations where identification and authentication have already occurred and are not repeated, but rather to situations where identification and authentication have not yet occurred. Organizations may decide that there are no user actions that can be performed on organizational information systems without identification and authentication have here of the controls CP-2, IA-2.	None	None
C-17 EMOTE ACCESS	The organization: a. Establishes and documents usage restrictions, configuration/connection requirements, and implementation guidance for each type of remote access allowed; and b. Authorizes remote access to the information system prior to allowing such connections.	A62.1, A62.2, A13.1.1, A13.2.1, A.14.1.2	broadband, and wireless. Organizations often employ encrypted virtual private networks (VPNs) to enhance confidentiality and integrity over remote connections. The use of encrypted VPNs does not make the access non-remote; however, the use of VPNs, when adequately provisioned with appropriate security controls (e.g., employing appropriate encryption techniques for confidentiality and integrity protection) may provide sufficient assurance to	The organization: (a) Authorizes the execution of privileged commands and access to security-relevant information via remote access only for [Assignment: organization-defined needs]; and (b) Documents the rationale for such access in the security plan for the information system. (c) SREMOTE ACCESS MONITORING FOR UNAUTHORIZED CONNECTIONS (S) REMOTE ACCESS MONITORING FOR UNAUTHORIZED CONNECTIONS (Withdrawn: incorporated into SI-4]. (6) REMOTE ACCESS PROTECTION OF INFORMATION The organization ensures that users protect information about remote access mechanisms from unauthorized use and disclosure. Supplemental Guidance: Related controls: AT-2, AT-3, F3-6. (7) REMOTE ACCESS ADDITIONAL PROTECTION FOR SECURITY FUNCTION ACCESS [Withdrawn: incorporated into AC-3 (10)]. (8) REMOTE ACCESS DISTRIBLE NONSECURE NETWORK PROTOCOLS [Withdrawn: incorporated into CM-7]. (9) REMOTE ACCESS DISTRIBLE NONSECURE NETWORK PROTOCOLS [Withdrawn: incorporated into CM-7]. (9) REMOTE ACCESS DISTRIBLE NONSECURE NETWORK PROTOCOLS [Withdrawn: incorporated into CM-7]. (9) REMOTE ACCESS DISTRIBLE NONSECURE NETWORK PROTOCOLS [Withdrawn: incorporated into CM-7]. (9) REMOTE ACCESS DISTRIBLE NONSECURE NETWORK PROTOCOLS [Withdrawn: incorporated into CM-7]. (9) REMOTE ACCESS DISTRIBLE ACCESS The organization provides the capability to expeditiously disconnect current users remotely accessing the information system and/or disable further remote access. The speed of disconnect or disablement varies based on the criticality of missions/Dusinssis functions and the need to eliminate immediate or future remote access to organizational information systems.	None
:-18 IRELESS ACCESS	The organization: a. Establishes usage restrictions, configuration/connection requirements, and implementation guidance for wireless access; and b. Authorizes wireless access to the information system prior to allowing such connections.	A62.1, A13.1.1, A132.1	Wireless technologies include, for example, microwave, packet radio (UHF/VHF), 802.11x, and Bluetooth, Wireless networks use authentication protocols (e.g., EAP/TLS, PEAP), which provide credential protection and mutual authentication. Related controls: AC-2, AC-3, AC-17, AC-19, CA-3, CA-7, CM-8, IA-2, IA-3, IA-8, PL-4, SI-4.	(1) WIRELESS ACCESS AUTHENTICATION AND ENCRYPTION The information system protects wireless accesses to the system using authentication of [Selection (one or more]: users; devices] and encryption. Supplemental Guidance: Related controls: SC-8, SC-13. (2) WIRELESS ACCESS MONTORING UNAUTHORIZED CONNECTIONS [Withdrawn: Incorporated into SI-4]. (3) WIRELESS ACCESS DISABLE WIRELESS NETWORKING The organization disables, when not intended for use, wireless networking capabilities internally embedded within information system components prior to issuance and deployment. Supplemental Guidance: Related control: AC-19. (4) WIRELESS ACCESS IDISABLE WIRELESS NETWORKING The organization identifies and explicitly authorizes users allowed to independently configure wireless networking capabilities. Supplemental Guidance: Related control: AC-3, SC-15. (5) WIRELESS ACCESS ACCESS	None
:-19 CCESS CONTROL FOR MOBILE DEVICES	The organization: a. Establishes usage restrictions, configuration requirements, connection requirements, and implementation guidance for organization-controlled mobile devices; and b. Authorizes the connection of mobile devices to organizational information systems.	A6.2.1, A.11.2.6, A.13.2.1	device to capture information, and/or built-in features for synchronizing local data with remote locations. Examples include smart phones, E-readers, and tablets. Mobile devices are typically associated with a single individual and the device is usually in close proximity to the individual; however, the degree of proximity can vary depending upon on the form factor and size of the device. The merely a subset of desktop systems, depending upon the nature and intended purpose of the device. Due to the large variety of mobile devices with different technical characteristics and capabilities, organizational restrictions may vary for the different classes/types of such devices. Usage restrictions and specific implementation guidance for mobile devices include, for example, configuration management, device identification and authentication, implementation of mandatory protective software (e.g., malicious code detection, firewall), scanning devices for malicious code, updating virus protection software, scanning for critical software updates and patches, conducting primary operating system (and possibly other resident software) integrity checks, and disabling unnecessary hardware (e.g., wireless, infrared). Organizations are cautioned that the need to provide adequate security for mobile devices pose beyond the requirements in this control. Many safeguards and countermeasures for mobile devices are reflected in other security controls in this control. Many safeguards and countermeasures for mobile devices are reflected in other security pans and overlays using the tailoring process. There may also be some degree of overlap in the requirements articulated by the security controls within the different families of controls & C-20 addresses mobile devices that are not organization.	(1) ACCESS CONTROL FOR MOBILE DEVICES USE OF WRITABLE / PORTABLE STORAGE DEVICES Withdrawn: incorporated into MP-7], (2) ACCESS CONTROL FOR MOBILE DEVICES USE OF PERSONALLY OWNED PORTABLE STORAGE DEVICES Withdrawn: incorporated into MP-7], (3) ACCESS CONTROL FOR MOBILE DEVICES USE OF PORTABLE STORAGE DEVICES WITH NO IDENTIFIABLE OWNER Withdrawn: incorporated into MP-7], (4) ACCESS CONTROL FOR MOBILE DEVICES USE OF PORTABLE STORAGE DEVICES WITH NO IDENTIFIABLE OWNER Withdrawn: incorporated into MP-7], (4) ACCESS CONTROL FOR MOBILE DEVICES RESTRICTIONS FOR CLASSIFIED INFORMATION The organization: (a) Prohibits the use of unclassified mobile devices in facilities containing information systems processing, storing, or transmitting classified information unless specifically permitted by the authorizing official; and (b) Enforces the following restrictions on individuals permitted by the authorizing official to use unclassified mobile devices in facilities containing information systems processing, storing, or transmitting classified information: (1) Connection of unclassified mobile devices to classified information systems is prohibited; (2) Connection of unclassified mobile devices to unclassified information systems requires approval from the authorizing official; (3) Use of internal or external or external modems or writeriess interfaces within the unclassified mobile devices is prohibited; and (4) Unclassified mobile devices and the information stored on those devices are subject to random reviews and inspections by [Assignment: organization-defined security officials], and if classified information is found, the incident handling policy is followed. (6) Restricts the connection of classified mobile devices to classified information systems in accordance with [Assignment: organization-defined security officials].	None

Doc Number: D0000003422
Tab: Controls and Guidance

Doc Number: D0000003422 Name: Product security standard assessment Revision: AB

Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
IC-21 NFORMATION SHARING	The organization: a Facilitates information sharing by enabling authorized users to determine whether access authorizations assigned to the sharing partner match the access restrictions on the information for [Assignment: organization-defined information sharing circumstances where user discretion is required]; and b. Employs [Assignment: organization-defined automated mechanisms or manual processes] to assist users in making information sharing/collaboration decisions.	None	This control applies to information that may be restricted in some manner (e.g., privileged medical information, contract-sensitive information, proprietary information, personally identifiable information, classified information related to special access programs or compartments) based on some formal or administrative determination. Depending on the particular information-sharing circumstances, sharing partners may be defined at the individual, group, or organizational level. Information may be defined by content, type, security category, or special access program/compartment. Related control: AC-3.	(1) INFORMATION SHARING AUTOMATED DECISION SUPPORT The information system enforces information-sharing decisions by authorized users based on access authorizations of sharing partners and access restrictions on information to be shared. (2) INFORMATION SHARING INFORMATION SEARCH AND RETRIEVAL The information system implements information search and retrieval services that enforce [Assignment: organization-defined information sharing restrictions].	None
C-23 ATA MINING PROTECTION	The organization employs [Assignment: organization-defined data mining prevention and detection techniques] for [Assignment: organization-defined data storage objects] to adequately detect and protect against data mining.	None	Data storage objects include, for example, databases, database records, and database fields. Data mining prevention and detection techniques include, for example: (1) limiting the types of responses provided to database queries; (ii) limiting the number/frequency of database queries to increase the work factor needed to determine the contents of such databases; and (iii) notifying organizational personnel when atypical database queries or accesses occur. This control focuses on the protection of organizational information from data mining while such information resides in organizational data stores. In contrast, AU-13 focuses on monitoring for organizational information that may have been mined or otherwise obtained from data stores and is now available as open source information residing on external sites, for example, through social networking or social media websites:	None	None
C-24 CCESS CONTROL DECISIONS	The organization establishes procedures to ensure [Assignment: organization-defined access control decisions] are applied to each access request prior to access enforcement.	A.9.4.1 (only partially satisfies NIST control)	Access control decisions (also known as authorization decisions) occur when authorization information is applied to specific accesses. In contrast, access enforcement occurs when information systems enforce access control decisions. While it is very common to have access control decisions and access enforcement implemented by the same entity, it is not required and it is not always an optimal implementation choice. For some architectures and distributed information systems, different entities may perform access control decisions and access enforcement.	(1) ACCESS CONTROL DECISIONS TRANSMIT ACCESS AUTHORIZATION INFORMATION The information system transmits [Assignment: organization-defined access authorization information information] using [Assignment: organization-defined security safeguards] to [Assignment: organization-defined information systems] that enforce access control decisions. Supplemental Guidance: In distributed information systems, authorization processes and access control decisions may occur in separate parts of the systems. In such instances, authorization information is transmitted security attributes. This is due to the fact that in distributed information systems, there are various access control decisions, that need to be made and different entities (e.g., services) make these decisions in a serial fashion, each requiring some security attributes to make the decisions. Protecting access authorization information (i.e., access control decisions) ensures that such information cannot be altered, spoofed, or otherwise compromised during transmission. (2) ACCESS CONTROL DECISIONS NO USER OR PROCESS IDENTITY The information system enforces access control decisions based on [Assignment: organization-defined security attributes] that do not include the identity of the user or process acting on behalf of the user. Supplemental Guidance: in certain situations, it is important that access control decisions can be made without information regarding the identity of the user is suing the requests. These are generally instances where preserving individual privacy is of paramount importance. In other situations, user identification information is simply not needed for access control decisions and, especially in the case of distributed information systems, transmitting auch information with the needed degree of assurance may be very expensive or difficult to accomplished.	None
F-1 CURITY AWARENESS AND TRAINING POLICY ND PROCEDURES	The organization: a Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A security awareness and training policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and compliance; and compliance; and compliance; and compliance; associated security awareness and training controls; and b. Reviews and updates the current: 1. Security awareness and training policy [Assignment: organization-defined frequency]: and 2. Security awareness and training procedures [Assignment: organization-defined frequency].	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A18.2.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the AT family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information socurity policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizationarisk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.	No.	None
T-2 CURITY AWARENESS TRAINING	The organization provides basic security awareness training to information system users (including managers, senior executives, and contractors): a. As part of initial training for new users; b. When required by information system changes; and c. [Assignment: organization-defined frequency] thereafter.	A7.2.2, A12.2.1	Organizations determine the appropriate content of security awareness training and security awareness techniques based on the specific organizational requirements and the information systems to which personnel have authorized access. The content includes a basic understanding of the need for information security and user actions to maintain security and to respond to suspected security incidents. The content also addresses awareness of the need for operations security. Security awareness techniques can include, for example, displaying posters, offering supplies inscribed with security reminders, generating email advisories/notices from senior organizational officials, displaying logon screen messages, and conducting information security awareness events. Related controls: AT-3, AT-4, PL-4.	Supplemental Guidance: Practical exercises may include, for example, no-notice social engineering attempts to collect information, gain unauthorized access, or simulate the adverse impact of opening malicious email	None s.
T-3 DLE-BASED SECURITY TRAINING	The organization provides role-based security training to personnel with assigned security roles and responsibilities: a. Before authorizing access to the information system or performing assigned duties; b. When required by information system changes; and c. [Assignment: organization-defined frequency] thereafter.	A.7.2.2 (only partially satisfies NIST control)	Organizations determine the appropriate content of security training based on the assigned roles and responsibilities of individuals and the specific security requirements of organizations and the information systems to which personnel have authorized access. In addition, organizations provide enterprise architects, information system developers, software developers, acquisition/procurement officials, information system managers, system/network administrators, personnel conducting configuration management and auditing activities, personnel performing independent verification and validation activities, security control assessors, and other personnel having access to system-level software, adequate security-related technical training specifically tailored for their assigned duties. Comprehensive role-based training addresses management, operational, and technical roles and responsibilities covering physical, personnel, and technical safeguards and countermeasures. Such training can include for example, policies, procedures, tools, and artifacts for the organizational security roles defined. Organizations also provide the training necessary for individuals to carry out their responsibilities related to operations and supply chain security within the context of organizational information security programs. Role-based security training also applies to contractors providing services to federal agencies. Related controls: AT-2, AT 4, PL-4, PS-7, SA-3, SA-12, SA-16.	(1) ROLE-BASED SECURITY TRAINING ENVIRONMENTAL CONTROLS The organization provides [Assignment: organization-defined personnel or roles] with initial and [Assignment: organization-defined frequency] training in the employment and operation of environmental controls. Supplemental Guidance: Environmental controls include, for example, fire suppression and detection devices/systems, sprinkler systems, handheld fire extinguishers, fixed fire hoses, smoke detectors, temperature/humidity HVAC, and power within the facility. Organizations identify personnel with specific roles and responsibilities associated with environmental controls requiring specialized training, Related controls. PE-1, PE-13, PE-14, PE-15 (2) ROLE-BASED SECURITY TRAINING PHYSICAL SECURITY CONTROLS The organization provided [Sasignment: organization-defined personnel or roles] with initial and [Assignment: organization-defined frequency] training in the employment and operation of physical security controls. Supplemental Guidance: Physical security controls include, for example, physical access control devices, physical intrusion alarms, monitoring/surveillance equipment, and security guards (deployment and operating procedures). Organizations identify personnel with specific roles and responsibilities associated with physical security controls requiring specialized training. Related controls: PE-2, PE-3, PE-4, PE-5. (3) ROLE-BASED SECURITY TRAINING PRACTICAL EXERCISES The organization includes practical exercises in security training that reinforce training objectives. Supplemental Guidance: Practical exercises any include, for example, security training for software developers that includes simulated cyber attacks exploiting common software vulnerabilities (e.g., buffer overflows), or spear/whale phishing attacks targeted at senior leaders/executives. These types of practical exercises help developers better understand the effects of such vulnerabilities and appreciate the need for security coding standards and processes. (4) ROLE-BASED S	None
J-1 IDIT AND ACCOUNTABILITY POLICY AND ROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. An audit and accountability policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the audit and accountability policy and associated audit and accountability controls; and b. Reviews and updates the current: 1. Audit and accountability policy [Assignment: organization-defined frequency]: and 2. Audit and accountability procedures [Assignment: organization-defined frequency].	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A182.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the AU family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizationarisk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
J-2 JDIT EVENTS	The organization: a. Determines that the information system is capable of auditing the following events: [Assignment: organization-defined auditable events]; b. Coordinates the security audit function with other organizational entities requiring audit- related information to enhance mutual support and to help guide the selection of auditable events: c. Provides a rationale for why the auditable events are deemed to be adequate to support after the-fact investigations of security incidents; and d. Determines that the following events are to be audited within the information system: [Assignment: organization-defined audited events (the subset of the auditable events defined in AU-2 a.) along with the frequency of (or situation requiring) auditing for each identified event].		An event is any observable occurrence in an organizational information system. Organizations identify audit events as those events which are significant and relevant to the security of information systems and the environments in which those systems operate in order to meet specific and ongoing audit needs. Audit events can include, for example, password changes, failed logons, or failed accesses related to information systems, administrative privilege usage, PIV credential usage, or third-party credential usage. In determining the set of auditable events, organizations consider the auditing appropriate for each of the security controls to be implemented. To balance auditing requirements with other information system meets, this control also requires identifying that subset of auditable events that are audited at a given point in time. For example, organizations may determine that information systems must have the capability to log every file access both successful and unsuccessful, but not activate that capability except for specific circumstances due to the potential burden on system performance. Auditing requirements, including the need for auditable events, may be referenced in other security controls and control enhancements. Organizations also include auditable events that are required by applicable federal laws, Executive Orders, directives, policies, regulations, and standards. Audit records can be generated at various levels of abstraction, including at the packet level as information traverses the network. Selecting the appropriate level of abstraction is a critical aspect of an audit capability and can facilitate the identification of root causes to problems. Organizations and edinition of auditable events, the auditing necessary to cover related events sust the steps in distributed, transaction-based processes (e.g., processes that are distributed across multiple organizations) and actions that occur in service-oriented architectures. Related controls: AC-6, AC-17, AU-3, AU-12, AM-4, MP-2, MP-4, SI-4	(1) AUDIT EVENTS COMPILATION OF AUDIT RECORDS FROM MULTIPLE SOURCES [Withdrawn: Incorporated into AU-12]. (2) AUDIT EVENTS SELECTION OF AUDIT EVENTS BY COMPONENT [Withdrawn: Incorporated into AU-12]. (3) AUDIT EVENTS REVIEWS AND UPDATES The organization reviews and updates the audited events [Assignment: organization-defined frequency]. Supplemental Guidance: Over time, the events that organizations believe should be audited may change. Reviewing and updating the set of audited events periodically is necessary to ensure that the current set is still necessary and sufficient. (4) AUDIT EVENTS PRIVILEGED FUNCTIONS [Withdrawn: Incorporated into AC-6 (9)].	None
U-3 ONTENT OF AUDIT RECORDS	The information system generates audit records containing information that establishes what type of event occurred, when the event occurred, the source of the event, the outcome of the event, and the identity of any individuals or subjects associated with the event.		Audit record content that may be necessary to satisfy the requirement of this control, includes, for example, time stamps, source and destination addresses, user/process identifiers, event descriptions, success/fall indications, filenames involved, and access control or flow control rules involved. Event outcomes can include indicators of even success or failure and event-specific results (e.g., the security state of the information system after the event occurred). Related controls: AU-2, AU-8, AU-12, SI-11.	(2) CONTENT OF AUDIT RECORDS CENTRALIZED MANAGEMENT OF PLANNED AUDIT RECORD CONTENT The information system provides centralized management and configuration of the content to be captured in audit records generated by [Assignment: organization-defined information system components]. Supplemental Guidance: This control enhancement requires that the content to be captured in audit records be configured from a central location (necessitating automation). Organizations coordinate the selection of require audit content to support the centralized management and configuration capability provided by the information system. Related controls: AU-6, AU-7.	None
U-4 UDIT STORAGE CAPACITY	The organization allocates audit record storage capacity in accordance with [Assignment: organization-defined audit record storage requirements].	A12.1.3	Organizations consider the types of auditing to be performed and the audit processing requirements when allocating audit storage capacity. Allocating sufficient audit storage capacity reduces the likelihood of such capacity being exceeded and resulting in the potential loss or reduction of auditing capability. Related controls: AU-2, AU-5, AU-6, AU-7, AU-11, SI-4.	[1] AUDIT STORAGE CAPACITY TRANSFER TO ALTERNATE STORAGE The information system off-loads audit records, fassignment: organization-defined frequency] onto a different system or media than the system being audited. Supplemental Guidance: Off-loading is a process designed to preserve the confidentiality and integrity of audit records by moving the records from the primary information system to a secondary or alternate system. It is a common process in information systems with limited audit storage capacity; the audit storage is used only in a transitory fashion until the system can communicate with the secondary or alternate system designated for storing the audit records, at which point the information is transferred.	None



Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
AU-5 RESPONSE TO AUDIT PROCESSING FAILURES	The information system: a. Alerts [Assignment: organization-defined personnel or roles] in the event of an audit processing failure; and b. Takes the following additional actions: [Assignment: organization-defined actions to be taken (e.g., shut down information system, overwrite oldest audit records, stop generating audit records)].		Audit processing failures include, for example, software/hardware errors, failures in the audit capturing mechanisms, and audit storage capacity being reached or exceeded. Organizations may choose to define additional actions for different audit processing failures (e.g., by type, by location, by severity, or a combination of sout factors). This control applies to each audit data storage repository (i.e., distinct information system component where audit records are stored), the total audit storage capacity of organizations (i.e., all audit data storage repositories combined), or both. Related controls: AU-4, SI-12.	(1) RESPONSE TO AUDIT PROCESSING FAILURES AUDIT STORAGE CAPACITY The information system provides a warning to [Assignment: organization-defined personnel, roles, and/or locations] within [Assignment: organization-defined time period] when allocated audit record storage volume reaches [Assignment: organization-defined personnel, roles, and/or locations] within [Assignment: organization-defined personnel, roles, and/or locations] when the following audit failure expectates. (2) RESPONSE TO AUDIT PROCESSING FAILURES] [REAL-TIME ALERTS The information system provides an alert in [Assignment: organization-defined personnel, roles, and/or locations] when the following audit failure events occur: [Assignment: organization-defined audit failure events requiring real-time alerts]. (3) RESPONSE TO AUDIT PROCESSING FAILURES] (CONFIGURABLE TRAFFIC VOLUME THRESHOLDS The information system provide organizations with urgent messages. Real-time alerts provide these messages are information technology speed (i.e., the time from event detection to alert occurs in seconds or less). (3) RESPONSE TO AUDIT PROCESSING FAILURES] (CONFIGURABLE TRAFFIC VOLUME THRESHOLDS The information system enforces configurable network communications traffic volume thresholds reflecting limits on auditing capacity and [Selection: rejects; delays] network traffic above those thresholds. Supplemental Guidance: Organizations have the capability to reprocessing of network communications traffic if auditing such traffic is determined to exceed the storage capacity of the information system audit function. The rejection or delay response is triggered by the established organizational traffic volume thresholds which can be adjusted based on changes to audit storage capacity. (4) RESPONSE TO AUDIT PROCESSING FAILURES SHIPTIOWN ON FAILURE The information system invokes a [Selection: full system shutdown; degraded operational mode with limited mission/business functionallity available] in the event of [Assignment: organization-defined audit failures],	ne
AU-6 AUDIT REVIEW, ANALYSIS, AND REPORTING	The organization: a. Reviews and analyzes information system audit records [Assignment: organization-defined frequency] for indications of [Assignment: organization-defined inappropriate or unusual activity]; and b. Reports findings to [Assignment: organization-defined personnel or roles].	A124.1, A16.1.2, A16.1.4	mobile device connection, configuration settings, system component inventory, use of maintenance tools and nonlocal maintenance, physicial access, temperature and humidity, equipment delivery and removal, communications at the information system boundaries, use of mobile code, and use of VoIP. Findings can be reported to organizational entities that include, for example, incident response team, help desk, information security group/department. If organizations are prohibited from reviewing and analyzing audit information or unable to conduct such activities (e.g., in certain national security applications or systems), the review/analysis may	[1] AUDIT REVIEW, ANALYSIS, AND REPORTING PROCESS INTEGRATION The organization employs automated mechanisms to integrate audit review, analysis, and reporting processes to support organizational processes be neiting from integrated audit review, analysis, and reporting include, for example, incident response, continuous monitoring, contingency planning, and Inspector General audits. Related controls: AU-12, PM-7. [2] AUDIT REVIEW, WARLYSIS, AND REPORTING AUTOMATED SECURITY ALERTS [Withdrawn: Incorporated into S1-4]. [3] AUDIT REVIEW, WARLYSIS, AND REPORTING CORRELATE AUDIT REPOSITORIES The organization analyzes and correlates audit records across different repositories to gain organization-wide situational awareness. And to a support organization analyzes and correlates audit records across different repositories to gain organization-wide situational awareness. And to a support organization analyzes and correlates audit records across different repositories to gain organization-wide situational awareness. And to a support organization awareness. Related controls: AU-12, IR-4. [4] AUDIT REVIEW, WARLYSIS, AND REPORTING CENTRAL REVIEW AND ANALYSIS The information system provides the capability to centrally review and analyzes include, for example, Security Information Management products. Related controls: AU-2, AU-12. [5] AUDIT REVIEW, MANLYSIS, AND REPORTING INTEGRATION / SCANNING AND MONITORING CAPABILITIES The organization integrates analysis of audit records with analysis of Selection (one or more): vulnerability scanning information; performance data; information system monitoring information; [Assignment: organization-defined data/information collected from other sources]] to further enhance the ability to identify inappropriate or unusual activity. Supplemental Guidance: This components as well as audit record organization specification of performance data and analysis specifies the eveloped by organizations (with localized script adjustments, as necessary) provides more cost-effective approache	ne
AU-7 AUDIT REDUCTION AND REPORT GENERATION	The information system provides an audit reduction and report generation capability that: a. Supports on-demand audit review, analysis, and reporting requirements and after-the-fact livestigations of security incidents; and b. Does not after the original content or time ordering of audit records.	None	Audit reduction is a process that manipulates collected audit information and organizes such information in a summary format that is more meaningful to analysts. Audit reduction and report generation capabilities do not always emanate from the same information system or from the same organizational entities conducting auditing activities. Audit reduction capability can include, for example, modern data mining techniques with advanced data filters to identify anomalous behavior in audit records. The report generation capability provided by the information system can generate customizable reports. Time ordering of audit records can be a significant issue if the granularity of the timestamp in the record is insufficient. Related control. AU-G.	system where the users have elevated privileese including the capability to execute privileed commands. Full text analysis refers to analysis that considers the full text of privileed commands (i.e., commands and all (1) AUDIT REDUCTION AND REPORT GENERATION AUTOMATIC PROCESSING The information system provides the capability to process audit records for events of interest based on [Assignment: organization-defined audit fields within audit records.] Supplemental Guidance: Events of interest can be identified by the content of specific audit record fields including, for example, identities of individuals, event types, event locations, event times, event dates, system resources involved, IP addresses involved, or information objects accessed. Organizations may define audit event criteria to any degree of granularity required, for example, locations selectable by general networking location (e.g., by network or subnetwork) or selectable by specific information system component. Related controls: AU-2, AU-12. (2) AUDIT REDUCTION AND REPORT GENERATION AUTOMATIC SORT AND SEARCH The information system provides the capability to sort and search audit records for events of interest based on the content of [Assignment: organization-defined audit fields within audit records]. Supplemental Guidance: Sorting and searching of audit records may be based upon the contents of audit record fields, for example: (i) date/time of events; (ii) user identifiers; (iii) Internet Protocol (IP) addresses involved in	ne
AU-8 TIME STAMPS	The information system: a. Uses internal system clocks to generate time stamps for audit records; and b. Records time stamps for audit records that can be mapped to Coordinated Universal Time (UTC) or Greenwich Mean Time (GMT) and meets [Assignment: organization-defined granularity of time measurement].	A1244	Time stamps generated by the information system include date and time. Time is commonly expressed in Coordinated Universal Time (UTC), a modern continuation of Greenwich Mean Time (GMT), or local time with an offset from UTC. Granularity of time measurements refers to the degree of synchronization between information system clocks and reference clocks, for example, clocks synchronizing within hundreds of milliseconds or within tens of milliseconds. Organizations may define different time granularities for different system components. Time service can also be critical to other security capabilities such as access control and identification and authentication, depending on the nature of the mechanisms used to support those capabilities. Related controls: AU-3, AU-12.	the event; (iv) type of event; or (v) event success/failure. (1) TIME STAMPS SYNCHRONIZATION WITH AUTHORITATIVE TIME SOURCE The information system: (a) Compares the internal information system clocks [Assignment: organization-defined frequency] with [Assignment: organization-defined authoritative time source]; and (b) Synchronizes the internal system clocks to the authoritative time source when the time difference is greater than [Assignment: organization-defined time period]. No Supplemental Guidance: This control enhancement provides uniformity of time stamps for information systems with multiple system clocks and systems connected over a network. (2) TIME STAMPS SECONDARY AUTHORITATIVE TIME SOURCE The information system identifies a secondary authoritative time source that is located in a different geographic region than the primary authoritative time source.	ne
AU-9 PROTECTION OF AUDIT INFORMATION	The information system protects audit information and audit tools from unauthorized access, modification, and deletion.	A124.2, A124.3, A181.3	Audit information includes all information (e.g., audit records, audit settings, and audit reports) needed to successfully audit information system activity. This control focuses on technical protection of audit information. Physical protection controls and physical and environmental protection controls. Related controls: AC-3, AC-6, MP-2, MP-4, PE-2, PE-3, PE-6.	(1) PROTECTION OF AUDIT INFORMATION HARDWARE WRITE-ONCE MEDIA The information system writes audit trails to hardware-enforced, write-once media. Supplemental Guidance: This control enhancement applies to the initial generation of audit trails (i.e., the collection of audit records that represents the audit information to be used for detection, analysis, and reporting purposes) and to the backup of those audit trails. The enhancement does not apply to the initial generation of audit records prior to being written to an audit trail. Write-once, read-many (WORM) media includes, for example, Compact Disk-Recordable (CD-R) and Digital Video Disk-Recordable (DVD-R). In contrast, the use of switchable write-protection media such as on tape cartridges or Universal Serial Bus (USB) drives results in write-protected, but not write-none, media. Related controls: AU-I, 4U-S. (2) PROTECTION OF AUDIT INFORMATION (AUDIT BACKUP ON SEPARATE PHYSICAL SYSTEMS / COMPONENTS The information system backs up audit records [Assignment: organization-defined frequency] onto a physically different system or system component than the system or component being audited. Supplemental Guidance: This control enhancement helps to ensure that a compromise of the information system back up audit records. Related controls: AU-4, AU-5, AU-11. (3) PROTECTION OF AUDIT INFORMATION (EXPYPTOGRAPHIC PROTECTION) The information system implements cryptographic mechanisms to protect the integrity of audit information include, for example, signed hash functions using asymmetric cryptography enabling distribution of the public key to verify the hash information while maintaining the confidentiality of the secret key used to generate the hash. Related controls: AU-10, SC-12, SC-13. (4) PROTECTION OF AUDIT INFORMATION ACCESS BY SUBSET OF PRIVILEGED USERS Supplemental Guidance: Individuals with privileged access to an information system and who are also the subject of an audit by that system, may affect the reliability of audit information by inhibiting a	ne
AU-10 NON-REPUDIATION	The information system protects against an individual (or process acting on behalf of an individual) falsely denying having performed [Assignment: organization-defined actions to be covered by non-repudiation].	None		(1) NON-REPUDATION ASSOCIATION OF IDENTITIES The information system: (a) Binds the identity of the information producer with the information to [Assignment: organization-defined strength of binding]; and (b) Provides the means for authorized individuals to determine the identity of the producer of the information. Supplemental Guidance: This control enhancement supports audit requirements that provide organizational personnel with the means to identify who produced specific information in the event of an information transfer. Organizations determine and approve the strength of the binding between the information producer and the information based on the security category of the information and relevant risk factors. Related controls: AC-4, AC-16. (2) NON-REPUDATION VALIDATE BINDING OF INFORMATION PRODUCER IDENTITY The information system: (a) Validates the binding of the information producer identity to the information at [Assignment: organization-defined frequency]; and (b) Performs [Assignment: organization-defined actions] in the event of a validation error. Supplemental Guidance: This control enhancement prevents the modification of information between production and review. The validation of bindings can be achieved, for example, by the use of cryptographic checksums. Organizations determine if validations are rine response to user requests or generated automatically. Related controls: AC-3, AC-4, AC-16. (3) NON-REPUDATION CHAIN OF CUSTODY The information system maintains reviewer/releaser identity and credentials within the established chain of custody for all information reviewed or released. Supplemental Guidance: Chain of custody is a process that tracks the movement of evidence through its collection, safeguarding, and analysis life cycle by documenting each person who handled the evidence, the date and time it was collected or transferred, and the purpose for the transfer. If the reviewer is a human or if the review function is automated but separate from the release/transfer function, t	ne

Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
AU-11 AUDIT RECORD RETENTION	The organization retains audit records for [Assignment: organization-defined time period consistent with records retention policy] to provide support for after-the-fact investigations of security incidents and to meet regulatory and organizational information retention requirements.	A124.1, A161.7	Organizations retain audit records until it is determined that they are no longer needed for administrative, legal, audit, or other operational purposes. This includes, for example, retention and availability of audit records relative to Freedom of Information Act (FOIA) requests, subpoenas, and law enforcement actions. Organizations develop standard categories of audit records relative to such types of actions and standard response processes for each type of action. The Autional Archives and Records Administration (NARA) General Records Schedules provide federal policy on record retention. Related controls: AU-4, AU-5, AU-9, MP-6.	(1) AUDIT RECORD RETENTION LONG-TERM RETRIEVAL CAPABILITY The organization employs [Assignment: organization-defined measures] to ensure that long-term audit records generated by the information system can be retrieved. Supplemental Guidance: Measures employed by organizations to help facilitate the retrieval of audit records include, for example, converting records to newer formats, retaining equipment capable of reading the records, and retaining necessary documentation to help organizational personnel understand how to interpret the records.	None
AU-12 AUDIT GENERATION	The information system: a. Provides audit record generation capability for the auditable events defined in AU-2 a. at [Assignment: organization-defined information system components]: b. Allows [Assignment: organization-defined personnel or roles] to select which auditable events are to be audited by specific components of the information system; and c. Generates audit records for the events defined in AU-2 d. with the content defined in AU-3.	A.12.4.1, A.12.4.3	Audit records can be generated from many different information system components. The list of audited events is the set of events for which audits are to be generated. These events are typically a subset of all events for which the information system is capable of generating audit records. Related controls: AC-3, AU-2, AU-3, AU-6, AU-7.	(1) AUDIT GENERATION [SYSTEM-WIDE / TIME-CORRELATED AUDIT TRAIL The information system components] into a system-wide (logical or physical) audit trail that is time-correlated to within [Assignment: organization-defined level of tolerance for the relationship between time stamps of individual records in the audit trail]. Supplemental Guidance: Audit trails are time-correlated if the time stamps in the individual audit records can be reliably related to the time stamps in other audit records to achieve a time ordering of the records within organizational tolerances. Related controls: AU-8, AU-12. (2) AUDIT GENERATION [STANDARDIZED FORMATS The information system produces a system-wide (logical or physical) audit trail composed of audit records in a standardized format. Supplemental Guidance: Audit information that is normalized to common standards promotes interoperability and exchange of such information between dissimilar devices and information systems. This facilitates production of event information that can be more readily analyzed and correlated. Standard formats for audit records include, for example, system log records and audit records compliant with Common Event Expressions (ICEE). If logging mechanisms within information systems on ot conform to standardized formats, systems may convert individual audit records into standardized formats when compiling system-wide audit trails. (3) AUDIT GENERATION [CHANGES EY AUTHORIZED INDIVIDIALS The information system provides the capability for [Assignment: organization-defined electable event criteria] within [Assignment: organization-defined selectable event criteria] within [Assignment: organization-defined selectable event criteria] within [Assignment: organization-defined of address certain threat situations. In addition, auditing as necessary to meet organization adjurements. Auditing that is limited to conserve information system components] based on [Assignment: organization-defined selectable event criteria] within [Assignment: organization and reporting	None
AU-13 MONITORING FOR INFORMATION DISCLOSURI	The organization monitors [Assignment: organization-defined open source information and/or information sites] [Assignment: organization-defined frequency] for evidence of unauthorized disclosure of organizational information.	None	Open source information includes, for example, social networking sites. Related controls: PE-3, SC-7.	(1) MONITORING FOR INFORMATION DISCLOSURE USE OF AITOMATED TOOLS The organization employs automated mechanisms to determine if organizational information has been disclosed in an unauthorized manner. Supplemental Guidance: Automated mechanisms can include, for example, automated scripts to monitor new posts on selected websites, and commercial services providing notifications and alerts to organizations. (2) MONITORING FOR INFORMATION DISCLOSURE REVIEW OF MONITORED SITES The organization reviews the open source information sites being monitored (Assignment: organization-defined frequency).	None
AU-14 SESSION AUDIT	The information system provides the capability for authorized users to select a user session to capture/record or view/hear.	control)	Session audits include, for example, monitoring keystrokes, tracking websites visited, and recording information and /or file transfers. Session auditing activities are developed, integrated, and used in consultation with legal counsel in accordance with applicable federal laws, Executive Orders, directives, policies, regulations, or standards. Related controls: AC-3, AU-4, AU-5, AU-9, AU-11.	(1) SESSION AUDIT SYSTEM START-UP The information system initiates session audits at system start-up. (2) SESSION AUDIT CAPTURE/RECORD AND LOG CONTENT The information system provides the capability for authorized users to capture/record and log content related to a user session. (3) SESSION AUDIT REMOTE VIEWING / LISTENING The information system provides the capability for authorized users to remotely view/hear all content related to an established user session in real time.	None
AU-15 ALTERNATE AUDIT CAPABILITY	The organization provides an alternate audit capability in the event of a failure in primary audit capability that provides [Assignment: organization-defined alternate audit functionality].	None	Since an alternate audit capability may be a short-term protection employed until the failure in the primary auditin, capability is corrected, organizations may determine that the alternate audit capability need only provide a subset of the primary audit functionality that is impacted by the failure. Related control: AU-5.		None
AU-16 CROSS-ORGANIZATIONAL AUDITING	The organization employs [Assignment: organization-defined methods] for coordinating [Assignment: organization-defined audit information] among external organizations when audit information is transmitted across organizational boundaries.	None	When organizations use information systems and/or services of external organizations, the auditing capability necessitates a coordinated approach across organizations. For example, maintaining the identity of individuals that requested particular services across organizational boundaries may often be very difficult, and doing so may prove to have significant performance ramifications. Therefore, it is often the case that cross-organizational auditing (e.g., the type of auditing capability provided by service-oriented architectures) simply captures the identity of individuals issuing requests at the initial information system, and subsequent systems record that the requests emanated from authorized individuals. Related control: AU-6.		None
CA-7 CONTINUOUS MONITORING	The organization develops a continuous monitoring strategy and implements a continuous monitoring program that includes: a. Establishment of [Assignment: organization-defined metrics] to be monitored; b. Establishment of [Assignment: organization-defined frequencies] for monitoring and [Assignment: organization-defined frequencies] for monitoring stock monitoring; c. Ongoing security control assessments in accordance with the organizational continuous monitoring strategy; d. Ongoing security status monitoring of organization-defined metrics in accordance with the organizational continuous monitoring strategy; e. Correlation and analysis of security-related information generated by assessments and monitoring; f. Response actions to address results of the analysis of security-related information; and g. Reporting the security status of organization and the information system to [Assignment: organization-defined frequency].	None	Continuous monitoring programs facilitate ongoing awareness of threats, vulnerabilities, and information security to support organizational risk management decisions. The terms continuous and ongoing imply that organizations assess/analyse security controls and information security-related risks at a frequency sufficient to support organizational risk-based decisions. The results of continuous monitoring programs generate appropriate risk response actions by organizations. Continuous monitoring programs also allow organizations to maintain the security authorizations of information systems and common controls over time in highly dynamic environments of operation with changing mission/business needs, threats, vulnerabilities, and technologies. Having access to security-related information on a continuing basis through reports/dashboards gives organizational officials the capability to make more effective and timely risk management decisions, including ongoing security authorization decisions. Automation supports more frequent updates to security authorization packages, hardware/software/firmware inventories, and other system information. Effectiveness is further enhanced when continuous monitoring outputs are formatted to provide information that is specific, measurable, actionable, relevant, and timely. Continuous monitoring activities are scaled in accordance with the security categories of information systems. Related controls: CA-2, CA-5, CA-6	Supplemental Guidance: Organizations can maximize the value of assessments of security controls during the continuous monitoring process by requiring that such assessments be conducted by assessors or assessment teams with appropriate levels of independence based on continuous monitoring strategies. Assessor independence provides a degree of impartiality to the monitoring process. To achieve such impartiality, assessors should not: (i) create a mutual or conflicting interest with the organizations where the assessments are being conducted; (ii) assess their own work; (iii) act as management or employees of the organizations they are serving; or (iv)	None
CM-1 CONFIGURATION MANAGEMENT POLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A configuration management policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the configuration management policy and associated configuration management controls; and b. Reviews and updates the current: 1. Configuration management policy [Assignment: organization-defined frequency]; and 2. Configuration management procedures [Assignment: organization-defined frequency].	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A18.2.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the CM family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizations risk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
CM-2 BASELINE CONFIGURATION	The organization develops, documents, and maintains under configuration control, a current baseline configuration of the information system.	None	This control establishes baseline configurations for information systems and system components including communications and connectivity-related aspects of systems. Baseline configurations are documented, formally reviewed and agreed-upon sets of specifications for information systems or configuration items within those systems. Baseline configurations serve as a basis for future builds, releases, and/or changes to information systems Baseline configurations include information about information system components (e.g., standard software packages installed on workstations, notebook computers, servers, network components or mobile devices; current version numbers and patch information on operating systems and applications; and configuration settings/parameters), network topology, and the logical placement of those components within the system architecture. Maintaining baseline configurations requires creating new baselines as organizational information systems change over time. Baseline configurations of information systems reflect the current enterprise architecture. Related controls: CM-3, CM-6, CM-9, CM-9, SA-10, PM-5, PM-7.	[1] BASELINE CONFIGURATION REVIEWS AND UPDATES The organization reviews and updates the baseline configuration of the information system: [a] JASSIgnment organization-defined frequency]; [b] When required due to [Assignment organization-defined circumstances]; and [c] As an integral part of information system component installations and upgrades. Supplemental Guidance: Related control: CM-S. [2] BASELINE CONFIGURATION AITOMATION SUPPORT FOR ACCURACY / CURRENCY The organization employs automated mechanisms to maintain an up-to-date, complete, accurate, and readily available baseline configuration of the information system. Supplemental Guidance: Automated mechanisms to maintain and up-to-date, complete, accurate, and readily available baseline configuration of the information system. Supplemental Guidance: Automated mechanisms to maintain and up-to-date, complete, accurate, and readily available baseline configuration of the information system applications, to the complete of the co	None



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CM-3 CONFIGURATION CHANGE CONTROL	The organization: a. Determines the types of changes to the information system that are configuration-controlled; b. Reviews proposed configuration-controlled changes to the information system and approves or disapproves such changes with explicit consideration for security impact analyses; c. Documents configuration change decisions associated with the information system; d. Implements approved configuration-controlled changes to the information system for [Assignment: organization-defined time period]; f. Audits and reviews activities associated with configuration-controlled changes to the information system; and g. Coordinates and provides oversight for configuration change control activities through [Assignment: organization-defined configuration change control element (e.g., committee, board]] that convenes [Selection (noe or more); [Assignment: organization-defined frequency]; [Assignment: organization-defined configuration change conditions]].	A.12.1.2, A.14.2.2, A.14.2.3, A.14.2.4	Configuration change controls for organizational information systems involve the systematic proposal, justification, implementation, testing, review, and disposition of changes to the systems, including system upgrades and modifications. Configuration configuration components and configuration teems of information systems, changes to configuration settings for information technology products (e.g., operating systems, applications, firewalls, routers, and mobile devices), unscheduled/unauthorized changes, and changes to remediate vulnerabilities. Typical processes for managing configuration changes to information systems include, for example, Configuration Control Boards that approve proposed changes to systems. For new development information systems or systems undergoing major upgrades, organizations consider including representatives from development organizations on the Configuration Control Boards. Auditing of changes includes activities before and after changes are made to organizational information systems and the auditing activities required to implement such changes. Related controls: CA-7, CM-2, CM-4, CM-5, CM-6, CM-9, SA-10, SI-2, SI-12.	replicated systems). (3) CONFIGURATION CHANGE CONTROL AUTOMATED CHANGE IMPLEMENTATION The organization employs automated mechanisms to implement changes to the current information system baseline and deploys the updated baseline across the installed base. (4) CONFIGURATION CHANGE CONTROL SECURITY REPRESENTATION The organization requires an information security representative to be a member of the [Assignment: organization-defined configuration change control element]. Supplemental Guidance: Information security representatives can include, for example, senior agency information security officers, information system security officers, or information system security officers, or information system security officers, one of which may be security managers. Representation by personnel with information security experies is important because changes to information system configurations can have unintended side effects, some of which may be security relevant. Detecting such changes early in the process can help avoid unintended, negative consequences that could ultimately affect the security state of organizational information systems. The configuration change control element in this control enhancement reflects the change control element defined by organizations in CM-3. (5) CONFIGURATION CHANGE CONTROL AUTOMATED SECURITY RESPONSE The information system implements [Assignment: organization-defined security is allowed and an unauthorized manner. Supplemental Guidance: Security responses include, for example, halting information system processing, halting selected system functions, or issuing alerts/notifications to organizational personnel when there is an unauthorized modification of a configuration temperation. (6) CONFIGURATION CHANGE CONTROL [CRYPTOGRAPHY MANAGEMENT The organization ensures that cryptographic means employed (e.g., public key, private key, shared secrets), organizations ensure that there are processes and procedures in place to effectively manage those	one
CM-4 SECURITY IMPACT ANALYSIS	The organization analyzes changes to the information system to determine potential security impacts prior to change implementation.	A1423	Organizational personnel with information security responsibilities (e.g., Information System Administrators, Information System Security Officers, Information System Security Managers, and Information System Security Engineers) conduct security impact analyses. Individuals conducting security impact analyses possess the necessary skills/technical expertise to analyze the changes to information systems and the associated security ramifications. Security impact analysis may include, for example, reviewing security plans to understand security control requirements and reviewing system design documentation to understand control implementation and how specific changes might affect the controls. Security impact analyses may also include assessments of risk to better understand the impact of the changes and to determine if additional security controls are required. Security impact analyses are scaled in accordance with the security categories of the information systems. Related controls: CA-2, CJ-7, CM-3, CM-9, SA-4, SA-5, SA-10, SI-2.	supplemental usual ance: separate test environment in its context means an environment that is physically or logically isolated and distinct from the operational environment and in formation in the operational environment is not inadvertently transmitted to the test environment activities in the operational environment is not inadvertently transmitted to the test environments can be achieved by physical or logical means. If physically separate test environments can be achieved by physical or logical means. If physically separate test environments can be achieved through virtual machines). Related controls: SA-11, SC-3, SC-7. (2) SECURITY IMPACT ANALYSIS VERIFICATION OF SECURITY FUNCTIONS The organization, after the information system is changed, checks the security functions to verify that the functions are implemented correctly, operating as intended, and producing the desired outcome with regard to meeting the security requirements for the system. Supplemental Guidance: Implementation is this context refers to installing changed code in the operational information system. Related control: SA-11.	one
CM-5 ACCESS RESTRICTIONS FOR CHANGE	The organization defines, documents, approves, and enforces physical and logical access restrictions associated with changes to the information system.	A9.2.3, A9.4.5, A12.1.2, A12.1.4, A12.5.1	Any changes to the hardware, software, and/or firmware components of information systems can potentially have significant effects on the overall security of the systems. Therefore, organizations permit only qualified and authorized individuals to access information systems for purposes of initiating changes, including upgrades and modifications. Organizations maintain records of access to ensure that configuration change control is implemented and to support affect-the-fact actions should organizations discover any unauthorized changes. Access restrictions for change also include software libraries. Access restrictions include, for example, physicial and logical access controls (see AC-3 and PE-3), workflow automation, media libraries, abstract layers (e.g., changes implemented into third-party interfaces rather than directly into information systems), and change windows (e.g., changes occur only during specified times, making unauthorized changes easy to discover). Related controls: AC-3, AC-6, PE-3.	pacs, evice arrivers, and task input output system (BIUS) updates. Organizations can identify applications controls CM-7, SC-13, SI-7. (4) ACCESS RESTRICTIONS FOR CHANGE DUAL AUTHORIZATION The organization enforces dual authorization for implementing changes to [Assignment: organization-defined information system components and system-level information]. Supplemental Guidance: Organizations employ dual authorization to ensure that any changes to selected information system components and information annot occur unless two qualified individuals implement such changes. The two individuals possess sufficient skills/expertise to determine if the proposed changes are correct implementations of approved changes. Dual authorization may also be known as two-person control. Related	one
CM-6 CONFIGURATION SETTINGS	The organization: a. Establishes and documents configuration settings for information technology products employed within the information system using [Assignment: organization-defined security configuration checklists] that reflect the most restrictive mode consistent with operational requirements; b. Implements the configuration settings; c. Identifies, documents, and approves any deviations from established configuration settings for [Assignment: organization-defined information system components] based on [Assignment: organization-defined operational requirements]; and d. Monitors and controls changes to the configuration settings in accordance with organizational policies and procedures.	None	Configuration settings are the set of parameters that can be changed in hardware, software, or firmware components of the information system that affect the security posture and/or functionality of the system. Information technology products for which security-related configuration settings can be defined include, for example, mainframe computers, servers (e.g., database, electronic mail, authentication, web, proxy, file, domain name), workstations, input/output devices (e.g., examers, copiers, and printers), network components (e.g., firewalls, routers, gateways, voice and data switches, wireless access points, network appliances, sensors), operating systems, middleware, and applications. Security-related parameters are those parameters impacting the security state of information systems including the parameters required to satisfy other security control requirements. Security-related parameters include, for example: (1) registry settings; (ii) account, file, directory permission settings; and (iii) settings for functions, ports, protocols, services, and remote connections. Organizations establish organization—wide configuration settings and subsequently derive specific settings for information systems. The established settings become part of the systems configuration baseline. Common secure configurations [also referred to as security configuration the devichts; s lockdown and hardening guides, security reference guides, security technical implementation guides) provide recognized, standardized, and established benchmarks that stipulate secure configuration strings or specific information technology product developers, manufacturers, vendors, consortia, academia, industry, federal agencies, and other organizations in the public and private sectors. Common secure configurations include the United States Government Configurations can be developed by a variety of organizations include the United States Government Configurations can be developed by a variety of organizations in clude the Controls such as AC-19 an	(1) CONFIGURATION SETTINGS AUTOMATED CENTRAL MANAGEMENT / APPLICATION / VERIFICATION The organization employs automated mechanisms to centrally manage, apply, and verify configuration settings for [Assignment: organization-defined information system components]. Supplemental Guidance: Relaxed controls: CA-7, CM-4. (2) CONFIGURATION SETTINGS RESPOND TO UNAUTHORIZED CHANGES The organization employs [Assignment: organization-defined security safeguards] to respond to unauthorized changes to [Assignment: organization-defined configuration settings]. Supplemental Guidance: Responses to unauthorized changes to configuration settings can include, for example, alerting designated organizational personnel, restoring established configuration settings, or in extreme cases, halting affected information system processing. Related controls: IR-4, S1-7. (3) CONFIGURATION SETTINGS UNAUTHORIZED CHANGE DETECTION [Withdrawn: Incorporated into SI-7]. (4) CONFIGURATION SETTINGS CONFORMANCE DEMONSTRATION [Withdrawn: Incorporated into CM-4].	one
CM-7 LEAST FUNCTIONALITY	The organization: a. Configures the information system to provide only essential capabilities; and b. Prohibits or restricts the use of the following functions, ports, protocols, and/or services: [Assignment: organization-defined prohibited or restricted functions, ports, protocols, and/or services].	A.12.5.1 (only partially satisfies NIST control)	Information systems can provide a wide variety of functions and services. Some of the functions and services, provided by default, may not be necessary to support essential organizational operations (e.g., key missions, functions). Additionally, it is sometimes convenient to provide multiple services from single information system components, but doing so increases risk over limiting the services provided by any one component. Where feasible, organizations limit component functionality to a single function per device (e.g., email servers or web servers, but not both). Organizations review functions and services provided by information systems or individual components of information systems, to determine which functions and services are candidates for elimination (e.g., Voice Over Internet Protocol, Instant Messaging, auto-execute, and file sharing). Organizations consider disabiling unused or unnecessary physical and logical ports/protocols (e.g., Universal Serial Bus, File Transfer Protocol, and Hyper Text Transfer Protocol) on information systems to prevent unauthorized connection of devices, unauthorized transfer of information, or unauthorized transfer of information, or unauthorized transfer of information, or unauthorized transfer of such safe review of the province o	and peer-to-peer networking are examples of less than secure protocols. Related controls: AC-18, CM-7, IA-2. (2) LEAST PUNCTIONALITY PREVENT PROGRAM EXECUTION The information system prevents program execution in accordance with [Selection (one or more): [Assignment: organization-defined policies regarding software program usage and restrictions]: rules authorizing the terms and conditions of software program usage]. [Supplemental Guidance: Related controls: CM-8, PM-5.	one



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CM-9 CONFIGURATION MANAGEMENT PLAN	The organization develops, documents, and implements a configuration management plan for the information system that: a. Addresses roles, responsibilities, and configuration management processes and procedures; b. Establishes a process for identifying configuration items throughout the system development life cycle and for managing the configuration of the configuration items; c. Defines the configuration items for the information system and places the configuration items under configuration management; and d. Protects the configuration management plan from unauthorized disclosure and modification.	A.6.1.1 (only partially satisfies NIST control)	Configuration management plans satisfy the requirements in configuration management policies while being tailored to individual information systems. Such plans define detailed processes and procedures for how configuration management is used to support system development life cycle activities at the information system level. Configuration management plans are typically developed during the development/acquisition phase of the system development life cycle. The plans describe how to move changes through change management processes, how to update configuration settings and baselines, how to maintain information system component inventories, how to control development, test, and operational environments, and how to develop, release, and update key documents. Organizations can employ templates to help ensure consistent and timely development and implementation of configuration management plans. Such templates can represent a master configuration management plans for the organization at large with subsets of the plan implemented on a system by system basis. Configuration management approval processes include designation of key management stakeholders responsible for reviewing and approving proposed changes to information systems, and personnel that conduct security impact analyses prior to the implementation of changes to the systems. Configuration items are the information system items (hardware, software, firmware, and documentation) to be configuration tems are the information system items (hardware, software, firmware, and documentation) to be configuration tems may be identified and some existing configuration items may be identified and some existing configuration items may no longer need to be under configuration control. Related controls: CM-2, CM-3, CM-4, CM-5, CM-8, SA-10.	(1) CONFIGURATION MANAGEMENT PLAN ASSIGNMENT OF RESPONSIBILITY The organization assigns responsibility for developing the configuration management process to organizational personnel that are not directly involved in information system development. Supplemental Guidance: In the absence of dedicated configuration management teams assigned within organizations, system developers may be tasked to develop configuration management processes using personnel who are not directly involved in system development or integration. This separation of duties ensures statulish and maintain a sufficient degree of independence between the information system development and integration processes and configuration management processes to facilitate quality control and more effective oversight.	None
CP-1 CONTINGENCY PLANNING POLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A contingency planning policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the contingency planning policy and associated contingency planning controls; and b. Reviews and updates the current: 1. Contingency planning policy [Assignment: organization-defined frequency]; and 2. Contingency planning rocedures [Assignment: organization-defined frequency].	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A18.2.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the CP family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizational risk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
CP-2 CONTINGENCY PLAN	The organization: a. Develops a contingency plan for the information system that: 1. Identifies essential missions and business functions and associated contingency requirements; 2. Provides recovery objectives, restoration priorities, and metrics; 3. Addresses contingency roles, responsibilities, assigned individuals with contact information; 4. Addresses maintaining essential missions and business functions despite an information system disruption, compromise, or failure; 5. Addresses eventual, full information system restoration without deterioration of the security safeguards originally planned and implemented; and 6. Is reviewed and approved by [Assignment: organization-defined personnel or roles]; b. Distributes copies of the contingency plan to [Assignment: organization-defined few contingency personnel (identified by name and/or by role) and organizational elements]; c. Coordinates contingency planning activities with incident handling activities; d. Reviews the contingency plan for the information system [Assignment: organization-defined frequency]; e. Updates the contingency plan to address changes to the organization, information system, or environment of operation and problems encountered during contingency plan implementation execution, or testing; f. Communicates contingency plan changes to [Assignment: organization-defined key contingency personnel (identified by name and/or by role) and organizational elements]; and g. Protects the contingency plan from unauthorized disclosure and modification.	A6.1.1, A17.1.1, A17.2.1	and implementation of alternative mission/business processes when systems are compromised. The effectiveness of contingency planning is maximized by considering such planning throughout the phases of the system development life cycle. Performing contingency planning on hardware, software, and firmware development can be an effective means of achieving information system resiliency. Contingency plans reflect the degree of restoration	The organization coordinates contingency plan development with organizational elements responsible for related plans. Supplemental Guidance: Plans related to contingency plans for organizational information systems include, for example, Business Continuity Plans, Disaster Recovery Plans, Continuity of Operations Plans, Crisis Communications Plans, Critical Infrastructure Plans, Cyber Incident Response Plans, Insider Threat Implementation Plan, and Occupant Emergency Plans. (2) CONTINGENCY PLAN CAPACITY PLANNING The organization conducts capacity planning so that necessary capacity for information processing telecommunications, and environmental support exists during contingency operations. Supplemental Guidance: Capacity planning is needed because different types of threats (e.g., natural disasters, targeted cyber attacks) can result in a reduction of the available processing, telecommunications, and support services originally intended to support the organizational missions/business functions. Organizations may need to anticipate degraded operations during contingency operations and factor such degradation into capacity planning. (3) CONTINEENCY PLAN RESUME ESSENTIAL MISSIONS / BUSINESS FUNCTIONS The organization plans for the resumption of essential missions shad business functions within [Assignment: organization of contingency plan activation. Supplemental Guidance: Organizations may hoose to carry out the contingency planning activities in this control enhancement as part of organizational business continuity planning including, for example, as part of business impact analyses. The time period for resumption of essential missions/business functions may be dependent on the severity/extent of disruptions to the information system and its supporting infrastructure. Related control: PE-12.	None
:P-3 :ONTINGENCY TRAINING	The organization provides contingency training to information system users consistent with assigned roles and responsibilities: a. Within [Assignment: organization-defined time period] of assuming a contingency role or responsibility; b. When required by information system changes; and c. [Assignment: organization-defined frequency] thereafter.	A.7.2.2 (only partially satisfies NIST control)	Contingency training provided by organizations is linked to the assigned roles and responsibilities of organizational personnel to ensure that the appropriate content and level of detail is included in such training. For example, regular users may only need to know when and where to report for duty during contingency operations and if normal duties are affected; system administrators may require additional training on how to set up information systems at alternate processing and storage sites; and managery/senior leaders may receive more specific training on how to conduct mission-essential functions in designated off-site locations and how to establish communications with other governmental entities for purposes of coordination on contingency-related activities. Training for contingency roles/responsibilities reflects the specific continuity requirements in the contingency plan. Related controls: AT-2, AT-3, CP.2, IR.	(1) CONTINGENCY TRAINING SIMULATED EVENTS The organization incorporates simulated events into contingency training to facilitate effective response by personnel in crisis situations. (2) CONTINGENCY TRAINING LAUTEMATED TRAINING ENVIRONMENTS.	ione
P-4 ONTINGENCY PLAN TESTING	The organization: a. Tests the contingency plan for the information system [Assignment: organization-defined frequency] using [Assignment: organization-defined tests] to determine the effectiveness of the plan and the organizational readiness to execute the plan; b. Reviews the contingency plan test results; and c. Initiates corrective actions, if needed.	A17.1.3	Methods for testing contingency plans to determine the effectiveness of the plans and to identify potential weaknesses in the plans include, for example, walk-through and tabletop exercises, checklists, simulations (parallel, full interrupt), and comprehensive exercises. Organizations conduct testing based on the continuity requirements in contingency plans and include a determination of the effects on organizational operations, assets, and individuals arising due to contingency operations. Organizations have flexibility and discretion in the breadth, depth, and timelines of corrective actions. Related controls: CP-2, CP-3, IR-3.		None
P-6 LTERNATE STORAGE SITE	The organization: a. Establishes an alternate storage site including necessary agreements to permit the storage and retrieval of information system backup information; and b. Ensures that the alternate storage site provides information security safeguards equivalent to that of the primary site.	A11.1.4, A.17.1.2, A.17.2.1	Alternate storage sites are sites that are geographically distinct from primary storage sites. An alternate storage site maintains duplicate copies of information and data in the event that the primary storage site is not available. Items covered by alternate storage site agreements include, for example, environmental conditions at alternate sites, access rules, physical and environmental protection requirements, and coordination of delivery/retrieval of backup media. Alternate storage sites reflect the requirements in contingency plans so that organizations can maintain essential missions/business functions despite disruption, compromise, or failure in organizational information systems. Related controls: CP-2, CP-7, CP-9, CP-10, MP-4.	omission/commission. Organizations determine what is considered a sunicient degree of separation between primary and alternate storage sites based on the types of threats that are of concern. For one particular type of threat (i.e., hostile cyber attack), the degree of separation between sites is less relevant. Related control: RA-3. [70] ALTERNATE STORAGE SITE IRECOVERY TIME / POINT DRIFFITURES.	None
P-7 LITERNATE PROCESSING SITE	The organization: a. Establishes an alternate processing site including necessary agreements to permit the transfer and resumption of [Assignment: organization-defined information system operations] for essential missions/business functions within [Assignment: organization-defined time period consistent with recovery time and recovery point objectives] when the primary processing capabilities are unavailable; b. Ensures that equipment and supplies required to transfer and resume operations are available at the alternate processing site or contracts are in place to support delivery to the site within the organization-defined time period for transfer/resumption; and c. Ensures that the alternate processing site provides information security safeguards equivalent to those of the primary site.	A11.1.4, A17.1.2, A17.2.1	personnel. Requirements are specifically allocated to alternate processing sites that reflect the requirements in	(1) ALTERNATE PROCESSING SITE SEPARATION FROM PRIMARY SITE The organization identifies an alternate processing site that is esperated from the primary processing site to reduce susceptibility to the same threats. Supplemental Guidance: Threats that affect alternate processing sites are typically defined in organizational assessments of risk and include, for example, natural disasters, structural failures, hostile cyber attacks, and errors of omission / commission. Organizations determine what is considered a sufficient degree of separation between primary and alternate processing sites based on the types of threats that are of concern. For one particular type of threat (i.e., bostile cyber attack), the degree of separation between sites is less relevant. Related control: RA-3. (2) ALTERNATE PROCESSING SITE ACCESSIBILITY The organization identifies potential accessibility problems to the alternate processing site in the event of an area-wide disruption or disaster and outlines explicit mitigation actions. Supplemental Guidance: Area-wide disruptions refer to those types of disruptions that are broad in geographic scope (e.g., hurricane, regional power outage) with such determinations made by organizations based on organizational assessments of risk. Related control: RA-3. (3) ALTERNATE PROCESSING SITE PRIORITY OF SERVICE. The organization develops alternate processing site agreements that contain priority-of-service provisions in accordance with organizational availability requirements (including recovery time objectives). Supplemental Guidance: Priority-of-service provisions and the supplements and the supplements of the distinct of the processing site agreements refer to negotiated agreements with service provisions are certain the assure that organizations receive priority treatment consistent with their availability requirements and the	ione

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Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
:P-8 ELECOMMUNICATIONS SERVICES	The organization establishes alternate telecommunications services including necessary agreements to permit the resumption of [Assignment: organization-defined information system operations] for essential missions and business functions within [Assignment: organization-defined time period] when the primary telecommunications capabilities are unavailable at either the primary or alternate processing or storage sites.		This control applies to telecommunications services (data and voice) for primary and alternate processing and storage sites. Alternate telecommunications services reflect the continuity requirements in contingency plans to maintain essential missions) business functions despite the loss of primary telecommunications services. Organizations may specify different time periods for primary/alternate sites. Alternate telecommunications service include, for example, additional organizational or commercial ground-based circuits/files or satellites in lieu of ground-based communications. Organizations consider factors such as availability, quality of service, and access when entering into alternate telecommunications agreements. Related controls: CP-2, CP-6, CP-7.	(1) TELECOMMUNICATIONS SERVICES PRIORITY OF SERVICE PROVISIONS The organization: (a) Develops primary and alternate telecommunications service agreements that contain priority-of-service provisions in accordance with organizational availability requirements (including recovery time objectives); and (b) Requests Telecommunications Service Priority for all telecommunications services used for national security emergency preparedness in the event that the primary and/or alternate telecommunications services are provided by a common carrier. Supplemental Guidance: Organizations consider the potential mission/business impact in situations where telecommunications services providers are servicing other organizations with similar priority-of-service provisions. (2) TELECOMMUNICATIONS SERVICES SINGLE POINTS OF FAILURE The organization obtains alternate telecommunications services to reduce the likelihood of sharing a single point of failure with primary telecommunications services. (3) TELECOMMUNICATIONS SERVICES SEPARATION OF PRIMARY / ALTERNATE PROVIDERS The organization obtains alternate telecommunications service from providers that are separated from primary service providers to reduce susceptibility to the same threats. Supplemental Guidance: Threats that affect telecommunications services are typically defined in organizational assessments of risk and include, for example, natural disasters, structural failures, hostile cyber/physical attacks, and errors of omission/commission. Organizations service provider in situations where the service provider can provide alternate telecommunications service meeting the separation needs addressed in the risk assessment. (4) TELECOMMUNICATIONS SERVICES PROVIDER CONTINGENCY PLAN The organization: (6) Requires primary and alternate telecommunications service providers to have contingency plans; (6) Requires primary and alternate telecommunications service providers to have contingency requirements; and (6) Obtains evidence of contingency testing/training by pro	
P-9 NFORMATION SYSTEM BACKUP	The organization: a. Conducts backups of user-level information contained in the information system [Assignment: organization-defined frequency consistent with recovery time and recovery point objectives]; b. Conducts backups of system-level information contained in the information system [Assignment: organization-defined frequency consistent with recovery time and recovery point objectives]; c. Conducts backups of information system documentation including security-related documentation [Assignment: organization-defined frequency consistent with recovery time and recovery point objectives]; and d. Protects the confidentiality, integrity, and availability of backup information at storage locations.	A.12.3.1, A.17.1.2, A.18.1.3	System-level information includes, for example, system-state information, operating system and application software, and licenses. User-level information includes any information other than system-level information. Mechanisms employed by organizations to protect the integrity of information system backups include, for example digital signatures and cryptographic hashes. Protection of system backup information while in transit is beyond the scope of this control. Information system backups reflect the requirements in contingency plans as well as other organizational requirements for backing up information. Related controls: CP-2, CP-6, MP-4, MP-5, SC-13.		None
:P-10 NFORMATION SYSTEM RECOVERY AND RECONSTITUTION	The organization provides for the recovery and reconstitution of the information system to a known state after a disruption, compromise, or failure.	A17.1.2	Recovery is executing information system contingency plan activities to restore organizational missions/business functions. Reconstitution takes place following recovery and includes activities for returning organizational information systems to fully operational states. Recovery and reconstitution operations reflect mission and business priorities, recovery point/time and reconstitution objectives, and established organizational metrics consistent with contingency plan requirements. Reconstitution includes the deactivation of any interim information system capabilities that may have been needed during recovery operations. Reconstitution also includes sassessments of fully restored information system capabilities, restablishment of continuous monitoring activities, potential information system reauthorizations, and activities to prepare the systems against future disruptions, compromises, or failures. Recovery/reconstitution capabilities employed by organizations can include both automated mechanisms and manual procedures. Related controls: CA-2, CA-6, CA-7, CP-2, CP-6, CP-7, CP-9, SC-24.	(1) INFORMATION SYSTEM RECOVERY AND RECONSTITUTION CONTINGENCY PLAN TESTING [Withdrawn: Incorporated into CP-4]. (2) INFORMATION SYSTEM RECOVERY AND RECONSTITUTION TRANSACTION RECOVERY The information system implements transaction recovery for systems that are transaction-based. Supplemental Guidance: Transaction-based information systems include, for example, database management systems and transaction processing systems. Mechanisms supporting transaction recovery include, for example, transaction rollback and transaction journaling. (3) INFORMATION SYSTEM RECOVERY AND RECONSTITUTION COMPENSATING SECURITY CONTROLS [Withdrawn: Addressed through tailoring procedures]. (4) INFORMATION SYSTEM RECOVERY AND RECONSTITUTION RESTORE WITHIN TIME PERIOD The organization provides the capability to restore information system components within [Assignment: organization-defined restoration time-periods] from configuration-controlled and integrity-protected information	None
P-13 LTERNATIVE SECURITY MECHANISMS	The organization employs [Assignment: organization-defined alternative or supplemental security mechanisms] for satisfying [Assignment organization-defined security functions] when the primary means of implementing the security function is unavailable or compromised.	A.17.1.2 (only partially satisfies NIST control)	This control supports information system resiliency and contingency planning/continuity of operations. To ensure mission/business continuity, organizations can implement alternative or supplemental security mechanisms. These mechanisms may be less effective than the primary mechanisms (e.g., not as easy to use, not as scalable, or not as secure). However, having the capability to readily employ these alternative/supplemental mechanisms enhances overall mission/business continuity that might otherwise be adversely impacted if organizational operations had to be curtailed until the primary means of implementing the functions was restored. Given the cost and level of effort required to provide such alternative capabilities, this control would typically be applied only to critical security capabilities provided by information systems, system components, or information system services. For example, an organization may issue to senior executives and system administrators one-time pads in case multifactor tokens, the organization's standard means for secure remote authentication, is compromised. Related control: CP-2.	None	None
A-1 DENTIFICATION AND AUTHENTICATION OLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or rotels]: 1. An identification and authentication policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the identification and authentication policy and associated identification and authentication controls; and b. Reviews and updates the current: 1. Identification and authentication policy [Assignment: organization-defined frequency]; and 2. Identification and authentication procedures [Assignment: organization-defined frequency].	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A182.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the IA family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organization-risk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None



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Revision: AB

		ISO/IEC 27001 Controls that fulfill			
Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
IA-2 IDENTIFICATION AND AUTHENTICATION (ORGANIZATIONAL USERS)	The information system uniquely identifies and authenticates organizational users (or processes acting on behalf of organizational users).	A92.1	Organizational users include employees or individuals that organizations deem to have equivalent status of employees (e.g., contractors, guest researchers). This control applies to all accesses other than: (i) accesses that are explicitly identified and documented in AC-14; and (ii) accesses that occur through authorized use of group authenticators without individual authentications may require unique identification of individuals in group accounts (e.g., shared privilege accounts) or for detailed accountability of individual activity. Organizations employ passwords, tokens, or biometrics to authenticate user identities, or in the case multifactor authentication, or some combination thereof. Access to organizational information systems by users (or processes acting on behalf of users) where such access is obtained by direct connections without the use of networks. Network access is access to organizational information systems by users (or processes acting on behalf of users) where such access is obtained through network connections (i.e., nonlocal accesses). Remote access is a type of network access that involves communication through external networks (e.g., the Internet). Internal networks include local area networks and wide area networks. In addition, the use of encrypted virtual private networks (VPRs) for network connections between organization-controlled endpoints and non-organization controlled endpoints may be treated as internal networks from the perspective of protecting the confidentiality and integrity of information traversing the network Organizations can satisfy the identification and authentication requirements in this control by complying with the requirements in Homeland Security Presidential Directive 12 consistent with the specific organization and implementation plans. Multifactor authentication requires the use of two or more different factors to achieve authentication. The factors are defined as: (i) something you know (e.g., cryptographic identification device, token): or (iii) somethi	(S) IDENTIFICATION AND AUTHENTICATION (GROUP AUTHENTICATION) The organization requires individuals to use individual authenticators as a second level of authentication in helps organizations to mitigate the risk of using group authenticators. (S) IDENTIFICATION AND DUTHENTICATION (IN EVTOWAR ACCESS TO PRIVILEGED ACCOUNTS - SEPRARTE DEVICE The information system implements multifactor authentication for network access to privileged accounts such that one of the factors is provided by a device separate from the system gaining access and the device meets [Assignment: organization-defined strength of mechanism requirements]. Supplemental Guidance: Related control: AC-6. (7) IDENTIFICATION AND AUTHENTICATION NETWORK ACCESS TO NON-PRIVILEGED ACCOUNTS - SEPRARTE DEVICE The information system implements multifactor authentication for network access to non-privileged accounts such that one of the factors is provided by a device separate from the system gaining access and the device meets [Assignment: organization-defined strength of mechanism requirements]. [8] IDENTIFICATION AND AUTHENTICATION INSTRUMENT ACCESS TO PRIVILEGED ACCOUNTS - REPLAY RESISTANT The information system implements replay-resistant authentication mechanisms for network access to privileged accounts. Supplemental Guidance: Authentication processes resist replay attacks if it is impractical to achieve successful authentications by replaying previous authentication messages. Replay-resistant techniques include, for example, protocols that use nonces or challenges such as Transport Layer Security (TLS) and time synchronous or challenge-response one-time authentication. [9] IDENTIFICATION AND AUTHENTICATION NETWORK ACCESS TO NON-PRIVILEGED ACCOUNTS - REPLAY RESISTANT The information system implements replay-resistant authentication mechanisms for network access to non-privileged accounts. Supplemental Guidance: Authentication processes resist replay attacks if it is impractical to achieve successful authentications by recording/replaying	
IA-4 IDENTIFIER MANAGEMENT	The organization manages information system identifiers by: a. Receiving authorization from [Assignment: organization-defined personnel or roles] to assign an individual, group, role, or device; b. Selecting an identifier that identifies an individual, group, role, or device; c. Assigning the identifier to the intended individual, group, role, or device; d. Preventing reuse of identifiers for [Assignment: organization-defined time period]; and e. Disabling the identifier after [Assignment: organization-defined time period of inactivity].	A9.2.1	Common device identifiers include, for example, media access control (MAC), Internet protocol (IP) addresses, or device-unique token identifiers. Management of individual identifiers is not applicable to shared information system accounts (e.g., guest and anonymous accounts). Typically, individual identifiers are the user names of the information system accounts assigned to those individuals. In such instances, the account management activities of AC-2 use account names provided by IA-4. This control also addresses individual identifiers not necessarily associated with information system accounts (e.g., identifiers used in physical security control databases accessed by badge reader systems for access to information systems). Preventing reuse of identifiers implies preventing the assignment of previously used individual, group, role, or device identifiers to different individuals, groups, roles, or devices. Related controls: AC-2, IA-2, IA-3, IA-5, IA-8, SC-37.	Supplemental Guidance: Characteristics identifying the status of individuals include, for example, contractors and foreign nationals. Identifying the status of individuals by specific characteristics provides additional information about the people with whom organizational personnel are communicating. For example, it might be useful for a government employee to know that one of the individuals on an email message is a contractor. Related control: AT-2. [5] IDENTIFIER MANAGEMENT DYNAMIC MANAGEMENT The information system dynamically manages identifiers. Supplemental Guidance: In contrast to conventional approaches to identification which presume static accounts for preregistered users, many distributed information system sincluding, for example, service-oriented architectures, rely on establishing identifiers at run time for entities that were previously unknown. In these situations, organizations anticipate and provision for the dynamic establishment of identifiers. Preestablished trust relationships and mechanisms with appropriate authorities to validate identifiers and related credentials are essential. AC-16. [6] IDENTIFIER MANAGEMENT CROSS-ORGANIZATION MANAGEMENT The organization orcordinates with [Assignment organization-effined external organization effined external organizations in effined external organization in efficiency or transmission of information. [7] IDENTIFIER MANAGEMENT IN-PERSON REGISTRATION The organization requires that the registration process to receive an individual identifier being issued because it requires the physical presence of individuals and actual face-to-face interactions with designated The organization organization requires that the registration process to receive an individual identifier being issued because it requires the physical presence of individuals and actual face-to-face interactions with designated The organization organization organization organization organization organization organization organization organization organization organization or	None
IA-5 AUTHENTICATOR MANAGEMENT	The organization manages information system authenticators by: a. Verifying, as part of the initial authenticator distribution, the identity of the individual, group, role, or device receiving the authenticator; b. Establishing initial authenticator content for authenticators defined by the organization; c. Ensuring that authenticators have sufficient strength of mechanism for their intended use; d. Establishing and implementing administrative procedures for initial authenticator distribution, for lost/compromised or damaged authenticators, and for revoking authenticators; e. Changing default content of authenticators prior to information system installation; f. Establishing minimum and maximum lifetime restrictions and reuse conditions for authenticators; g. Changing/refreshing authenticators [Assignment: organization-defined time period by authenticator type]; h. Protecting authenticator content from unauthorized disclosure and modification; l. Requiring individuals to take, and having devices implement, specific security safeguards to protect authenticators; and j. Changing authenticators for group/role accounts when membership to those accounts changes.	A9.2.1, A9.2.4, A9.3.1, A9.4.3	authenticator content is the actual content (e.g., the initial password) as opposed to requirements about authenticator content (e.g., minimum password length). In many cases, developers ship information system components with factory default authentication credentials to allow for initial installation and configuration. Defaul authentication protect individual authenticators may be implemented via control PL-4 or PS-6 for authenticators in the possession of individuals and by controls A.C.3, A.C.6, and S.C.28 for authenticators stored within organizational information systems (e.g., passwords stored in hashed or encrypted formats, files containing encrypted or hashed passwords accessible with administrator privileges). Information systems support individual authenticator management by organization-defined settings and restrictions for various authenticator characteristics including, for example, minimum password length, password composition, validation time window for time synchronous one-time tokens, and number of allowed rejections during the verification stage of biometric authenticators. Specific actions that can be taken to safeguard authenticators include, for example, maintaining possession of individual authenticators, not loaning or sharing individual authenticators with others, and reporting lost, stolen, or compromised authenticators in immediately. Authenticator management includes issuing and revolving, when no longer needed, authenticators for temporary access such as that required for remote maintenance. Device authenticators include, for example, certificates and passwords. Related controls: AC-2, AC-3, AC-6, CM-6, IA-2, IA-4, IA-8, PL-4, PS-5, PS-6, SC-12, SC-13, SC-17, SC-28.	The information system, for PKI-based authentication: (a) Validates certifications by constructing and verifying a certification path to an accepted trust anchor including checking certificate status information; (b) Enforces subthorized access to the corresponding private key; (c) Maps the authenticated identity to the account of the individual or group; and (d) Implements a local cache for revocation data to support path discovery and validation in case of inability to access revocation information via the network. Supplemental Guidance: Status information for certification paths includes, for example, certificate revocation lists or certificate status protocol responses. For PIV cards, validation of certifications involves the construction and verification path to the Common Policy Root trust anchor including certificate policy processing. Related control: IA-6. (3) AUTHENTICATOR MANAGEMENT IN-PERSON OR TRUSTED THIRD-PARTY REGISTRATION The organization requires that the registration process to receive [Assignment: organization-defined types of and/or specific authenticators] be conducted [Selection: in person; by a trusted third party] before [Assignment: organization-defined registration authority] with authorization by [Assignment: organization-defined personnel or roles].	None
IA-7 CRYPTOGRAPHIC MODULE AUTHENTICATIO	The information system implements mechanisms for authentication to a cryptographic module that meet the requirements of applicable federal laws, Executive Orders, directives, policies, regulations, standards, and guidance for such authentication.	A.18.1.5	Authentication mechanisms may be required within a cryptographic module to authenticate an operator accessing the module and to verify that the operator is authorized to assume the requested role and perform services within that role. Related controls: SC-12, SC-13.	None	None



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IA-8 IDENTIFICATION AND AUTHENTICATION (NON ORGANIZATIONAL USERS)	. The information system uniquely identifies and authenticates non-organizational users (or processes acting on behalf of non-organizational users).	A92.1	Non-organizational users include information system users other than organizational users explicitly covered by IA 2. These individuals are uniquely identified and authenticated for accesses other than those accesses explicitly identified and documented in AC-14. In accordance with the E-Authentication E-Government initiative, authentication of non-organizational users accessing federal information systems may be required to protect federal, proprietary, or privacy-related information (with exceptions noted for national security systems). Organizations user isk assessments to determine authentication needs and consider scalability, practicality, and security in balancing the need to ensure ease of use for access to federal information and information systems with the need to protect and adequately mitigate risk. IA-2 addresses identification and authentication requirements for access to information systems by organizational users. Related controls: AC-2, AC-14, AC-17, AC-18, IA-2, IA-4, IA-5, MA-4, RA-3, SA-12, SC-8.	The information system conforms to FICAM-issued profiles.	None
IA-9 SERVICE IDENTIFICATION AND AUTHENTICATION	The organization identifies and authenticates [Assignment: organization-defined information system services] using [Assignment: organization-defined security safeguards].	None	This control supports service-oriented architectures and other distributed architectural approaches requiring the identification and authentication of information system services. In such architectures, external services often appear dynamically. Therefore, information systems should be able to determine in a dynamic manner, if external providers and associated services are authentic. Safeguards implemented by organizational information systems to validate provider and service authenticity include, for example, information or code signing, provenance graphs, and/or electronic signatures indicating or including the sources of services.	(1) SERVICE IDENTIFICATION AND AUTHENTICATION INFORMATION EXCHANGE The organization ensures that service providers receive, validate, and transmit identification and authentication information. (2) SERVICE IDENTIFICATION AND AUTHENTICATION TRANSMISSION OF DECISIONS The organization ensures that identification and authentication decisions are transmitted between [Assignment: organization-defined services] consistent with organizational policies. Supplemental Guidance: For distributed architectures (e.g., service-oriented architectures), the decisions regarding the validation of identification and authentication claims may be made by services separate from the services acting on those decisions. In such situations, it is necessary to provide the identification and authentication decisions (as opposed to the actual identifiers and authenticators) to the services that need to act on those decisions. Related control: SC-8.	None
IA-10 ADAPTIVE IDENTIFICATION AND AUTHENTICATION	The organization requires that individuals accessing the information system employ [Assignment: organization-defined supplemental authentication techniques or mechanisms] under specific [Assignment: organization-defined circumstances or situations].	None	Adversaries may compromise individual authentication mechanisms and subsequently attempt to impersonate legitimate users. This situation can potentially occur with any authentication mechanisms employed by organizations. To address this threat, organizations may employ specific techniques/mechanisms and establish protocols to assess suspicious behavior (e.g., individuals accessing information that they do not typically access as part of their normal duties; notes, or responsibilities, accessing greater quantities of information than the individual would routinely access, or attempting to access information from suspicious network addresses). In these situation when certain preestablished conditions or triggers occur, organizations can require selected individuals to provide additional authentication in formation. Another potential use for adaptive identification and authentication in formation. Another potential use for adaptive identification and authentication is formation. Authentication in formation and international conditions are require selected individuals to provide additional authentication in formation. Another potential use for adaptive identification and authentication in formation. Another potential use for adaptive identification and authentication in formation. Another potential use for adaptive identification and authentication in formation. Authentication in formation and the provide additional authentication in formation.		None
IA-11 RE-AUTHENTICATION	The organization requires users and devices to re-authenticate when [Assignment: organization-defined circumstances or situations requiring re-authentication].	None	In addition to the re-authentication requirements associated with session locks, organizations may require re-authentication of individuals and/or devices in other situations including, for example: (I) when authenticators change; (II), when roles change; (III) when security categories of information systems change; (IV) when the execution of privileged functions occurs; (v) after a fixed period of time; or (vi) periodically. Related control: AC-11.	None	None
IR-1 INCIDENT RESPONSE POLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. An incident response policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the incident response policy and associated incident response controls; and b. Reviews and updates the current: 1. Incident response policy [Assignment: organization-defined frequency]: and 2. Incident response procedures [Assignment: organization-defined frequency].	A5.1.1,A5.1.2,A6.1.1,A12.1.1 A.18.1.1, A.18.2.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the IR family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizations risk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.	None	None
IR-2 INCIDENT RESPONSE TRAINING	The organization provides incident response training to information system users consistent with assigned roles and responsibilities: a. Within [Assignment: organization-defined time period] of assuming an incident response role or responsibility; b. When required by information system changes; and c. [Assignment: organization-defined frequency] thereafter.	A.7.2.2 (only partially satisfies NIST control)	Incident response training provided by organizations is linked to the assigned roles and responsibilities of organizational personnel to ensure the appropriate content and level of detail is included in such training. For example, regular users may only need to know who to call or how to recognize an incident on the information system; system administrators may require additional training on how to handle/remediate incidents; and incident responders may receive more specific training on forensics, reporting, system recovery, and restoration. Incident response training includes user training in the identification and reporting of suspicious activities, both from external and internal sources. Related controls: AT-3, CP-3, IR-8.	(1) INCIDENT RESPONSE TRAINING SIMULATED EVENTS The organization incorporates simulated events into incident response training to facilitate effective response by personnel in crisis situations. (2) INCIDENT RESPONSE TRAINING AUTOMATED TRAINING ENVIRONMENTS The organization employs automated mechanisms to provide a more thorough and realistic incident response training environment.	None

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IR-3 INCIDENT RESPONSE TESTING	The organization tests the incident response capability for the information system [Assignment: organization-defined frequency] using [Assignment: organization-defined tests] to determine the incident response effectiveness and documents the results.	None	Organizations test incident response capabilities to determine the overall effectiveness of the capabilities and to identify potential weaknesses or deficiencies. Incident response testing includes, for example, the use of checklists, walk-through or tabletop exercises, simulations (parallel/full interrupt), and comprehensive exercises. Incident response testing can also include a determination of the effects on organizational operations (e.g., reduction in mission capabilities), organizational assets, and individuals due to incident response. Related controls: CP-4, IR-8.	(1) INCIDENT RESPONSE TESTING AUTOMATED TESTING The organization employs automated mechanisms to more thoroughly and effectively test the incident response capability. Supplemental Guidance: Organizations use automated mechanisms to more thoroughly and effectively test incident response capabilities, for example: (i) by providing more complete coverage of incident response issues; (ii) by selecting more realistic test scenarios and test environments; and (iii) by stressing the response capability. Related control: AT-2. (2) INCIDENT RESPONSE TESTING CORDINATION WITH RELATED PLANS The organization coordinates incident response testing with organizational elements responsible for related plans. Supplemental Guidance: Organizational plans related to incident response testing include, for example, Business Continuity Plans, Contingency Plans, Disaster Recovery Plans, Continuity of Operations Plans, Crisis	None
IR-4 INCIDENT HANDLING	The organization: a. Implements an incident handling capability for security incidents that includes preparation, detection and analysis, containment, eradication, and recovery; b. Coordinates incident handling activities with contingency planning activities; and c. Incorporates lessons learned from ongoing incident handling activities into incident response procedures, training, and testing, and implements the resulting changes accordingly.	A161.4, A161.5, A161.6	Organizations recognize that incident response capability is dependent on the capabilities of organizational information systems and the mission/business processes being supported by those systems. Therefore, organizations consider incident response as part of the definition, design, and development of mission/business processes and information systems. Incident-related information can be obtained from a variety of sources including, for example, audit monitoring, network monitoring, physical access monitoring, user/administrator reports, and reported supply chain events. Effective incident handling capability includes coordination among many organizational entities including, for example, mission/business owners, information system owners, authorizing officials, human resources offices, physical and personnel security offices, legal departments, operations personnel, procurement offices, and the risk executive (function). Related controls: AU-6, CM-6, CP-2, CP-4, IR-2, IR-3, IR-8, PE-6, SC-5, SC-7, SI-3, SI-4, SI-7.	(5) INCIDENT HANDLING AUTOMATIC DISABLING OF INFORMATION SYSTEM The organization implements a configurable capability to automatically disable the information system if [Assignment: organization-defined security violations] are detected. (6) INCIDENT HANDLING INSIDER THERATS. SPECIFIC CAPABILITIES The organization implements incident handling capability in insider threats. Supplemental Guidance: While many organizations address insider threat incidents as an inherent part of their organizational incident response capability, this control enhancement provides additional emphasis on this type of threat and the need for specific incident handling capabilities [as defined within organizations] to provide appropriate and timely responses. (7) INCIDENT HANDLING INSIDER THERATS. INTRA-ORGANIZATION CORDINATION The organization coordinates incident handling in single threats across [Assignment: organization-defined components or elements of the organization]. Supplemental Guidance: Incident handling for insider threat incidents (including preparation, detection and analysis, containment, eradication, and recovery) requires close coordination among a variety of organizational components or elements to be effective. These components or elements include, for example, mission/business owners, information system owners, human resources offices, porcardent offices, operations personnel, and risk executive (function). In addition, organizations may require external support from federal, state, and local law enforcement agencies. (8) INCIDENT HANDLING CORRELATION WITH EXTERNAL ORGANIZATIONS The organization coordinates with [Assignment organization-defined external organizations and are federed external organizations and organizations and organizations and organizations and organizations including for example, mission/business partners, military/coalition partners, customers, and multitiered developers, can provide significant benefits. Cross-organizations to leverage critical information from a variety of sources t	None
IR-5 INCIDENTMONITORING	The organization tracks and documents information system security incidents.	None	Documenting information system security incidents includes, for example, maintaining records about each incident, the status of the incident, and other pertinent information necessary for forensics, evaluating incident details, trends, and handling, Incident information can be obtained from a variety of sources including, for example, incident reports, incident response teams, audit monitoring, network monitoring, physical access monitoring, and user/administrator reports. Belated controls: 41.6, 18-8, 19-6, 5C-5, 5C-7, 51-3, 51-4, 51-7.	(1) INCIDENT MONITORING AUTOMATED TRACKING / DATA COLLECTION / ANALYSIS The completion complete output of mechanisms to cold in the residence and on the collection and analysis of feedback information.	None
IR-6 INCIDENT REPORTING	The organization: a. Requires personnel to report suspected security incidents to the organizational incident response capability within [Assignment: organization-defined time period]; and b. Reports security incident information to [Assignment: organization-defined authorities].	A.6.1.3, A.16.1.2	The intent of this control is to address both specific incident reporting requirements within an organization and the formal incident reporting requirements for federal agencies and their subordinate organizations. Suspected security incidents include, for example, the receipt of suspicious email communications that can potentially contain malicious code. The types of security incidents reported, the content and timeliness of the reports, and the designated reporting authorities reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Current federal policy requires that all federal agencies (unless specifically exempted from such requirements) report security incidents to the United States Computer Emergency Readiness Team (US-CERT) within specified time frames designated in the US-CERT Concept of Operations for Federal Cyber Security Incident Handling, Related controls: IR-4, IR-5, IR-8.	ine or gameaton employs autonated metalisms to assist in the reporting or security incidents. Supplemental Guidance: Related control: IR-7. (2) INCIDENT REPORTING VULNERABILITIES RELATED TO INCIDENTS The organization reports information system vulnerabilities associated with reported security incidents to [Assignment: organization-defined personnel or roles]. (3) INCIDENT REPORTING COORDINATION WITH SUPPLY CHAIN The organization reports incident security incidents associated with reported security incidents to [Assignment: organization-defined personnel or roles].	None
IR-7 INCIDENT RESPONSE ASSISTANCE	The organization provides an incident response support resource, integral to the organizational incident response capability that offers advice and assistance to users of the information system for the handling and reporting of security incidents.	None	Incident response support resources provided by organizations include, for example, help desks, assistance groups, and access to forensics services, when required. Related controls: AT-2, IR-4, IR-6, IR-8, SA-9.	(1) INCIDENT RESPONSE ASSISTANCE, JAUTOMATION SUPPORT FOR AVAILABILITY OF INFORMATION / SUPPORT The organization employs automated mechanisms to increase the availability of incident response-related information and support. Supplemental Guidance: Automated mechanisms can provide a push and/or pull capability for users to obtain incident response assistance. For example, individuals might have access to a website to query the assistance capability, or conversely, the assistance capability may have the ability to proactively send information to users (general distribution or targeted) as part of increasing understanding of current response capabilities and	None
IR-8 Incident response plan	The organization: a. Develops an incident response plan that: 1. Provides the organization with a roadmap for implementing its incident response capability; 2. Describes the structure and organization of the incident response capability; 3. Provides a high-level approach for how the incident response capability fits into the overall organization; 4. Meets the unique requirements of the organization, which relate to mission, size, structure, and functions; 5. Defines reportable incidents; 6. Provides metrics for measuring the incident response capability within the organization; 7. Defines the resources and management support needed to effectively maintain and mature an incident response capability; and 8. Is reviewed and approved by [Assignment: organization-defined personnel or roles]; b. Distributes copies of the incident response plan to [Assignment: organization-defined incident response personnel (identified by name and/or by role) and organizational elements]; c. Reviews the incident response plan [Assignment: organization-defined frequency]; d. Updates the incident response plan to address system/organizational changes or problems encountered during plan implementation, execution, or testing; e. Communicates incident response plan changes to [Assignment: organization-defined incident response personnel (identified by name and/or by role) and organizational elements]; and f. Protects the incident response plan from unauthorized disclosure and modification.		It is important that organizations develop and implement a coordinated approach to incident response. Organizational missions, business functions, strategies, goals, and objectives for incident response help to determine the structure of incident response capabilities. As part of a comprehensive incident response capability, organizations consider the coordination and sharing of information with external organizations, including, for example, extremal service providers and organizations involved in the supply chain for organizational information systems. Related controls: MP-2, MP-4, MP-5.	None	None
IR-9 INFORMATION SPILLAGE RESPONSE	The organization responds to information spills by: a. Identifying the specific information involved in the information system contamination; b. Alerting [Assignment: organization-defined personnel or roles] of the information spill using a method of communication not associated with the spill; c. Isolating the contaminated information system or system component; d. Eradicating the information from the contaminated information system or component; e. Identifying other information systems or system components that may have been subsequently contaminated; and f. Performing other [Assignment: organization-defined actions].	None	Information spillage refers to instances where either classified or sensitive information is inadvertently placed on information systems that are not authorized to process such information. Such information spills often occur when information that is initially thought to be of lower sensitivity is transmitted to an information system and then is subsequently determined to be of higher sensitivity. At that point, corrective action is required. The nature of the organizational response is generally based upon the degree of sensitivity of the spilled information (e.g., security category or classification level), the security capabilities of the information system, the specific nature of contaminated storage media, and the access authorizations (e.g., security clearances) of individuals with authorized access to the contaminated system. The methods used to communicate information about the spill after the fact do not involve methods directly associated with the actual spill to minimize the risk of further spreading the contamination before such contamination is isolated and eradicated.		None
IR-10 INTEGRATED INFORMATION SECURITY ANALYSIS TEAM	The organization establishes an integrated team of forensic/malicious code analysts, tool developers, and real-time operations personnel.	None	Having an integrated team for incident response facilitates information sharing. Such capability allows organizational personnel, including developers, implementers, and operators, to leverage the team knowledge of the threat in order to implement defensive measures that will enable organizations to deter intrusions more effectively. Moreover, it promotes the rapid detection of intrusions, development of appropriate mitigations, and the deployment of effective defensive measures. For example, when an intrusion is detected, the integrated security analysis team can rapidly develop an appropriate response for operators to implement, correlate the new incident with information on past intrusions, and augment ongoing intelligence development. This enables the team to identify adversary TTPs that are linked to the operations tempo or to specific missions/business functions, and to define responsive actions in a way that does not disrupt the mission/business operations. Ideally, information security analysis teams are distributed within organizations to make the capability more resilient.	None	None

Tab: Controls and Guidance

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Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
MA-1 SYSTEM MAINTENANCE POLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A system maintenance policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the system maintenance policy and associated system maintenance controls; and b. Reviews and updates the current: 1. System maintenance procedures [Assignment: organization-defined frequency]: and 2. System maintenance procedures [Assignment: organization-defined frequency].		This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the MA family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizationarisk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
MA-2 CONTROLLED MAINTENANCE	The organization: a. Schedules, performs, documents, and reviews records of maintenance and repairs on information system components in accordance with manufacturer or vendor specifications and/or organizational requirements; b. Approves and monitors all maintenance activities, whether performed on site or remotely and whether the equipment is serviced on site or removed to another location; c. Requires that [Assignment: organization-defined personnel or roles] explicitly approve the removal of the information system or system components from organizational facilities for off-site maintenance or repairs; d. Sanitizes equipment to remove all information from associated media prior to removal from organizational facilities for off-site maintenance or repairs; e. Checks all potentially impacted security controls to verify that the controls are still functioning properly following maintenance or repair actions; and I includes [Assignment: organization-defined maintenance-related information] in organizational maintenance records.	control), A.11.2.5 (only partially satisfies NIST control)	such as scanners, copiers, and printers. Information necessary for creating effective maintenance records includes, for example: (i) date and time of maintenance; (ii) ame of individuals or group performing the maintenance; (iii) name of escort, if necessary; (iv) a description of the maintenance performed; and (v) information system components/equipment removed or replaced (including identification numbers, if applicable). The level of detail	(2) CONTROLLED MAINTENANCE AUTOMATED MAINTENANCE ACTIVITIES The organization: (a) Employs automated mechanisms to schedule, conduct, and document maintenance and repairs; and (b) Produces up-to date, accurate, and complete records of all maintenance and repair actions requested, scheduled, in process, and completed.	None
MA-3 MAINTENANCE TOOLS	The organization approves, controls, and monitors information system maintenance tools.	None	repair actions on organizational information systems. Maintenance tools can include hardware, software, and firmware items. Maintenance tools are potential vehicles for transporting malicious code, either intentionally or unintentionally, into a facility and subsequently into organizational information systems. Maintenance tools can	(a) Verifying that there is no organizational information contained on the equipment;	None
MA-4 NONLOCAL MAINTENANCE	The organization: a. Approves and monitors nonlocal maintenance and diagnostic activities; b. Allows the use of nonlocal maintenance and diagnostic tools only as consistent with organizational policy and documented in the security plan for the information system; c. Employs strong authenticators in the establishment of nonlocal antienance and diagnostic sessions; d. Maintains records for nonlocal maintenance and diagnostic activities; and e. Terminates session and network connections when nonlocal maintenance is completed.	None	Nonlocal maintenance and diagnostic activities are those activities conducted by individuals communicating through a network, either an external network (e.g., the Internet) or an internal network. Local maintenance and diagnostic activities are those activities carried out by individuals physically present at the information system or information system component and not communicating across a network connection. Authentication techniques used in the establishment of nonlocal maintenance and diagnostic sessions reflect the network access requirements in IA-2. Typically, strong authentication requires authenticators that are resistant to replay attacks and employ multifactor authentication. Strong authenticators include, for example, PkI where certificates are stored on a token protected by a password, passphrase, or biometric. Enforcing requirements in Ma-4 is accomplished in part by other controls. Related controls: AC-2, AC-3, AC-6, AC-17 AU-2, AU-3, IA-2, IA-4, IA-5, IA-8, MA-2, MA-5, MP-6, PL-2, SC-7, SC-10, SC-17.	(1) NONLOCAL MAINTENANCE AUDITING AND REVIEW The organization: (a) Audits nonlocal maintenance and diagnostic sessions [Assignment: organization-defined audit events]; and (b) Reviews the records of the maintenance and diagnostic sessions. Supplemental Guidance: Related controls: AU-2, AU-6, AU-12. (2) NONLOCAL MAINTENANCE DOCUMENT NONLOCAL MAINTENANCE The organization documents in the security plan for the information system, the policies and procedures for the establishment and use of nonlocal maintenance and diagnostic connections. (3) NONLOCAL MAINTENANCE COMPARABLE SECURITY SANTITATION The organization documents in the security plan for the information system, the policies and procedures for the establishment and use of nonlocal maintenance and diagnostic connections. (3) NONLOCAL MAINTENANCE COMPARABLE SECURITY SANTITATION The organization: (a) Requires that nonlocal maintenance and diagnostic services be performed from an information system that implements a security capability comparable to the capability implemented on the system being serviced; or (b) Removes the component to be serviced from the information system prior to nonlocal maintenance or diagnostic services, sanitizes the component (with regard to organizational information) before removal from organizational facilities, and after the service is performed, inspects and sanitizes the component (with regard to potentially mailcious offware) before reconnecting the component to the information system. Supplemental Guidance: Comparable security capability on information systems, diagnostic tools, and equipment are at least as comprehensive as the controls on the information system being serviced. Related controls: MA-3, SA-12, SI-3, SI-7. (4) NONLOCAL MAINTENANCE AUTHENTICATION / SPARATION of MAINTENANCE SESSIONS The organization protects nonlocal maintenance sessions from other network sessions with the information system by either: (1) Physically separated communications paths, or	None
MA-5 MAINTENANCE PERSONNEL	The organization: a. Establishes a process for maintenance personnel authorization and maintains a list of authorized maintenance organizations or personnel; b. Ensures that non-escorted personnel performing maintenance on the information system have required access authorizations; and c. Designates organizational personnel with required access authorizations and technical competence to supervise the maintenance activities of personnel who do not possess the required access authorizations.	None	This control applies to individuals performing hardware or software maintenance on organizational information systems, while PE-2 addresses physical access for individuals whose maintenance duties place them within the physical protection perimeter of the systems (e.g., custodial staff, physical plant maintenance personnel). Technical competence of supervising individuals relate to the maintenance performed on the information systems while having required access authorizations refers to maintenance on and near the systems. Individuals not previously identified as authorized maintenance personnel, such as information technology manufacturers, vendors, systems integrators, and consultants, may require privileged access to organizational information systems, for example, when required to conduct maintenance activities with little or no notice. Based on organizational assessments of risk, organizations may issue temporary credentials to these individuals. Temporary credentials may be for one-time use or for very limited time periods. Related controls: AC-2, IA-8, MP-2, PE-2, PE-3, PE-4, RA-3.	The organization ensures that personnel performing maintenance and diagnostic activities on an information system processing, storing, or transmitting classified information possess security clearances and formal access approvals for at least the highest classification level and for all compartments of information on the system.	

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Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
MA-6 TIMELY MAINTENANCE	The organization obtains maintenance support and/or spare parts for [Assignment: organization-defined information system components] within [Assignment: organization-defined time period] of failure.	(SP 800-53, r4, Appendix H)	Organizations specify the information system components that result in increased risk to organizational operations and assets, individuals, other organizations, or the Nation when the functionality provided by those components is not operational. Organizational actions to obtain maintenance support typically include having appropriate contracts in place. Related controls: CM-8, CP-2, CP-7, SA-14, SA-15.	(1) TIMELY MAINTENANCE PREVENTIVE MAINTENANCE The organization performs preventive maintenance on [Assignment: organization-defined information system components] at [Assignment: organization-defined time intervals]. Supplemental Guidance: Preventive maintenance includes proactive care and servicing of organizational information systems components for the purpose of maintaining equipment and facilities in satisfactory operating condition. Such maintenance provides for the systematic inspection, tests, measurements, adjustments, parts replacement, detection, and correction of incipient failures either before they occur or before they develop into major defects. The primary goal of preventive maintenance is ovoid/mitigate the consequences of equipment failures. Preventive maintenance is designed to preserve and restore equipment reliability by replacing worn components before they actually fail. Methods of determining what preventive (or other) failure management policies to apply include, for example, original equipment manufacturer (OEM) recommendations, statistical failure records, requirements of codes, legislation, or regulations within a jurisdiction, expert opinion, maintenance and conducted on similar equipment, or measured values and performance indications. (2) TIMELY MAINTENANCE PREDICTIVE MAINTENANCE The organization performs predictive maintenance or (Assignment: organization-defined time intervals). Supplemental Guidance: Predictive maintenance at a scheduled point in time when the maintenance activity is most cost-effective and before the equipment to separation of predictive component of predictive maintenance activities will be appropriate. Most predictive maintenance activities will be appropriate. Most predictive maintenance in the equipment of the equipment is never to equipment of statistical process control to determine at what point in the future maintenance activities will be appropriate. Most predictive maintenance can result in substantial cost savings and higher system reliabilit	None
MP-1 MEDIA PROTECTION POLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A media protection policy that addresses purpose, scope, roles, responsibilities, managemen commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the media protection policy and associated media protection controls; and b. Reviews and updates the current: 1. Media protection policy [Assignment: organization-defined frequency]; and 2. Media protection procedures [Assignment: organization-defined frequency].	t A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A18.2.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the MP family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizationarisk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
MP-2 MEDIA ACCESS	The organization restricts access to [Assignment: organization-defined types of digital and/or non-digital media] to [Assignment: organization-defined personnel or roles].	A8.2.3, A8.3.1, A.11.2.9	Information system media includes both digital and non-digital media. Digital media includes, for example, disketters, magnetic tapse, external/removable hard disk drives, flash drives, compact disks, and digital video disks. Non-digital media includes, for example, paper and microfilm. Restricting non-digital media access includes, for example, denying access to patient medical records in a community hospital unless the individuals seeking access to such records are authorized healthcare providers. Restricting access to digital media includes, for example, limiting access to design specifications stored on compact disks in the media library to the project leader and the individuals on the development team. Related controls. 46-53. Jac. Ju M-9, PE-5, PE-5, PI-5.	(Z) MEDIA ACLESS CKYFTOGKAPHIC PROTECTION Milyblorum, Incompanying (1911)	None
MP-4 MEDIA STORAGE	The organization: a. Physically controls and securely stores [Assignment: organization-defined types of digital and/or non-digital media] within [Assignment: organization-defined controlled areas]; and b. Protects information system media until the media are destroyed or sanitized using approved equipment, techniques, and procedures.	A823, A83.1, A112.9	Information system media includes both digital and non-digital media. Digital media includes, for example, diskettes, magnetic tapes, external/removable hard disk drives, flash drives, compact disks, and digital video disks. Non-digital media includes, for example, paper and microfilm. Physically controlling information system media includes, for example, conducting inventories, ensuring procedures are in place to allow individuals to check out and	(1) MEDIA STORAGE CRYPTOGRAPHIC PROTECTION [Withdrawn: Incorporated into SC-28 (1)]. [2) MEDIA STORAGE AUTOMATED RESTRICTED ACCESS The organization employs automated mechanisms to restrict access to media storage areas and to audit access attempts and access granted.	None
AP-7 AEDIA USE	The organization [Selection: restricts; prohibits] the use of [Assignment: organization-defined types of information system media] on [Assignment: organization-defined information system: or system components] using [Assignment: organization-defined security safeguards].	s A823,A83.1	Information system media includes both digital and non-digital media. Digital media includes, for example, diskettes, magnetic tapes, external/removable hard disk drives, flash drives, compact disks, and digital video disks. Non-digital media includes, for example, appear and microfilm. This control also applies to mobile devices with information storage capability (e.g., smart phones, tablets, E-readers). In contrast to MP-2, which restricts user access to media on information systems, for example, access to media a information systems, for example, restricting/prohibiting the use of flash drives or external hard disk drives. Organizations can employ technical and nontechnical safeguards (e.g., policies, procedures, rules of behavior) for vestrict the use of information system media. Organizations may restrict the use of portable storage devices, for example, by using physical cages on workstations to prohibit access to certain external ports, or disabling/removing the ability to insert, read or write to such devices. Organizations may also limit the use of portable storage devices to only approved devices including, for example, devices provided by the organization, devices provided by other approved organizations, and devices that are not personally owned. Finally, organizations may are strict the use of portable storage devices based on the type of device, for example, prohibiting the use of writeable, portable storage devices and implementing this restriction by disabiling or removing the capability to write to such devices. Related controls. Aci-19, PL-4.	(1) MEDIA USE PROHIBIT USE WITHOUT OWNER The organization prohibits the use of portable storage devices in organizational information systems when such devices have no identifiable owner. Supplemental Guidance: Requiring identifiable owners (e.g., individuals, organizations, or projects) for portable storage devices reduces the risk of using such technologies by allowing organizations to assign responsibility and accountability for addressing known vulnerabilities in the devices (e.g., malicious code insertion), Related control: PL-4. (2) MEDIA USE PROHIBIT USE OF SANITIZATION-RESISTANT MEDIA The organization prohibits the use of sanitization-resistant media in organizational information systems. Supplemental Guidance: Sanitization-resistant media in purge information from media. Certain types of media do not support sanitize commands, or if supported, the interfaces are not supported in a standardized way across these devices. Sanitization-resistant media include, for example, compact flash, embedded flash on boards and devices, solid state drives, and USB removable media. Related control: MP-6.	None
MP-8 MEDIA DOWNGRADING	The organization: a. Establishes [Assignment: organization-defined information system media downgrading process] that includes employing downgrading mechanisms with [Assignment: organization-defined strength and integrity]: b. Ensures that the information system media downgrading process is commensurate with the security category and/or classification level of the information to be removed and the access authorizations of the potential recipients of the downgraded information; c. Identifies [Assignment: organization-defined information system media requiring downgrading]; and d. Downgrades the identified information system media using the established process.	None	This control applies to all information system media, digital and non-digital, subject to release outside of the organization, whether or not the media is considered removable. The downgrading process, when applied to system media, removes information from the media, typically by security category or classification level, such that the information cannot be retrieved or reconstructed. Downgrading of media includes redacting information to enable wider release and distribution. Downgrading of media also ensures that empty space on the media (e.g., slack space within files) is devoid of information.	(1) MEDIA DOWNGRADING DOCUMENTATION OF PROCESS The organization documents information system media downgrading actions. Supplemental Guidance: Organization system media downgrading process by providing information such as the downgrading technique employed, the identification number of the downgraded media, and the identity of the individual that authorized and/or performed the downgrading action. (2) MEDIA DOWNGRADING EQUIPMENT TESTING The organization employs [Assignment: organization-defined tests] of downgrading equipment and procedures to verify correct performance [Assignment: organization-defined frequency]. (3) MEDIA DOWNGRADING CONTROLLED UNCLASSIFIED INFORMATION The organizationi downgrades information system media containing [Assignment: organization-defined Controlled Unclassified Information (CUI)] prior to public release in accordance with applicable federal and organizational standards and policies. (4) MEDIA DOWNGRADING CLASSIFIED INFORMATION The organization downgrades information system media containing classified information prior to release to individuals without required access authorizations in accordance with NSA standards and policies. Supplemental Guidance: Downgrading of classified information systems to unclassified media.	None
PE-1 PHYSICAL AND ENVIRONMENTAL PROTECT OLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A physical and environmental protection policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 10 2. Procedures to facilitate the implementation of the physical and environmental protection policy and associated physical and environmental protection controls; and b. Reviews and updates the current: 1. Physical and environmental protection policy [Assignment: organization-defined frequency] and 2. Physical and environmental protection procedures [Assignment: organization-defined frequency].	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A18.2.2 ;	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the PE family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizationa risk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
PE-2 PHYSICAL ACCESS AUTHORIZATIONS	The organization: a. Develops, approves, and maintains a list of individuals with authorized access to the facility where the information system resides; b. Issues authorization credentials for facility access; c. Reviews the access list detailing authorized facility access by individuals [Assignment: organization-defined frequency]; and d. Removes individuals from the facility access list when access is no longer required.	A.11.1.2 (only partially satisfies NIST control)	This control applies to organizational employees and visitors. Individuals (e.g., employees, contractors, and others) with permanent physical access authorization credentials are not considered visitors. Authorization credentials include, for example, badges, identification cards, and smart cards. Organizations determine the strength of authorization credentials needed (including level of forge-proof badges, smart cards, or identification cards) consistent with federal standards, policies, and procedures. This control only applies to areas within facilities that have not been designated as publicly accessible. Related controls: PE-3, PE-4, PS-3.	(1) PIYSICAL ACCESS AUTHORIZATIONS ACCESS BY POSITION / ROLE The organization authorizes physical access to the facility where the information system resides based on position or role. Supplemental Guidance: Related controls: AC-2, AC-3, AC-6. (2) PIYSICAL ACCESS AUTHORIZATIONS TWO FORMS OF IDENTIFICATION The organization requires two forms of identification from [Assignment: organization-defined list of acceptable forms of identification for visitor access to the facility where the information system resides. Supplemental Guidance: Acceptable forms of government photo identification include, for example, passports, Personal Identity Verification (PIV) cards, and drivers' licenses. In the case of gaining access to facilities using automated mechanisms, organizations may use PIV cards, key cards, PINS, and biometrics. Related controls: 1A-2, 1A, 1S- (3) PIYSICAL ACCESS AUTHORIZATIONS RESTRICT UNISCORTED ACCESS The organization or estricts unscorted access to the facility where the information system resides to personnel with [Selection (one or more): security clearances for all information contained within the system; formal access authorizations for all information contained within the system; information contained within the system; information contained within the system; formal access authorizations for all information contained within the system; information contained within the system; information contained within the system; information defined credentials]. Supplemental Guidance: Due to the highly sensitive nature of classified information is not exposed or otherwise compromised. Related controls: PS-2, PS-6.	None

Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
PE-3 PHYSICAL ACCESS CONTROL	The organization: a. Enforces physical access authorizations at [Assignment: organization-defined entry/exit points to the facility where the information system resides] by; 1. Verifying individual access authorizations before granting access to the facility; and 2. Controlling ingress/geres to the facility using [Selection (one or more): [Assignment: organization-defined physical access control systems/devices]; guards]; b. Maintains physical access audit logs for [Assignment: organization-defined entry/exit points]; c. Provides [Assignment: organization-defined security safeguards] to control access to areas within the facility officially designated as publicly accessible; d. Escorts visitors and monitors visitor activity [Assignment: organization-defined circumstances requiring visitor escorts and monitoring]; e. Secures keys, combinations, and other physical access devices; f. Inventories [Assignment: organization-defined physical access devices] every [Assignment: organization-defined frequency], and g. Changes combinations and keys [Assignment: organization-defined frequency] and/or when keys are lost, combinations are compromised, or individuals are transferred or terminated.	A11.1.1, A11.1.2, A11.1.3	administrative staff or information system users. Physical access devices include, for example, keys, locks, combinations, and card readers. Safeguards for publicly accessible areas within organizational facilities include, for example, cameras, monitoring by guards, and isolating selected information systems and/or system components in secured areas. Physical access control systems comply with applicable federal laws. Executive Orders, directives, policies, regulations, standards, and guidance. The Federal Identity, Credential, and Access Management Program provides implementation guidance for identity, credential, and access management capabilities for physical access control systems. Organizations have flexibility in the types of audit logs employed. Audit logs can be procedural (e.g. a written log of individuals accessing the facility and when such access occurred), automated (e.g., capturing ID provided by a PIV card), or some combination thereof. Physical access points can include facility access points, interior access points to information systems and/or components requiring supplemental access controls, or both. Components of organizational information systems (e.g., workstations, terminas) may be located in areas	[2] PIYSICAL ACCESS CONTROL FACILITY / INFORMATION SYSTEM BOUNDARIES so The organization performs security checks [Assignment: organization-defined frequency] at the physical boundary of the facility or information system for unauthorized exfiltration of information or removal of information system components. Supplemental Guidance: Organizations determine the extent, frequency, and/or randomness of security checks to adequately mitigate risk associated with exfiltration. Related controls: AC-4, SC-7. [3] PHYSICAL ACCESS CONTROL CONTINUOUS GUARDS / ALARMS / MONITORING The organization employs guards and/or alarms to monitor every physical access point to the facility where the information system resides 24 hours per day, 7 days per week. Supplemental Guidance: Related controls: CP-6, CP-7. [4] PHYSICAL ACCESS CONTROL LOCKABLE CASINGS, The organization uses lockable physical casings to protect [Assignment: organization-defined information system components] from unauthorized physical access. [5] PHYSICAL ACCESS CONTROL TAMPER PROTECTION The organization employ [Sasignment: organization-defined security safeguards] to [Selection (one or more): detect; prevent] physical tampering or alteration of [Assignment: organization-defined hardware components]	None
PE-4 ACCESS CONTROL FOR TRANSMISSION MEDIUM	The organization controls physical access to [Assignment: organization-defined information system distribution and transmission lines] within organizational facilities using [Assignment: organization-defined security safeguards].	A11.1.2, A11.2.3	Physical security safeguards applied to information system distribution and transmission lines help to prevent accidental damage, disruption, and physical tampering. In addition, physical safeguards may be necessary to help prevent eavesdropping or in transit modification of unencrypted transmissions. Security safeguards to control physical access to system distribution and transmission lines include, for example: (1) locked wiring closets; (ii) disconnected or locked spare jacks; and/or (iii) protection of cabling by conduit or cable trays. Related controls: MF 2, MP-4, PE-2, PE-3, PE-5, SC-7, SC-8.	None	None
PE-5 ACCESS CONTROL FOR OUTPUT DEVICES	The organization controls physical access to information system output devices to prevent unauthorized individuals from obtaining the output.	A11.1.2, A11.1.3	Controlling physical access to output devices includes, for example, placing output devices in locked rooms or other secured areas and allowing access to authorized individuals only, and placing output devices in locations that can b monitored by organizational personnel. Monitors, printers, copiers, scanners, facsimile machines, and audio device are examples of information system output devices. Related controls: PE-2, PE-3, PE-4, PE-18.	The information system:	None
PE-6 MONITORING PHYSICAL ACCESS	The organization: a. Monitors physical access to the facility where the information system resides to detect and respond to physical access logs [Assignment: organization-defined frequency] and upon occurrence of [Assignment: organization-defined events or potential indications of events]; and c. Coordinates results of reviews and investigations with the organizational incident response capability.	None	Organizational incident response capabilities include investigations of and responses to detected physical security incidents. Security incidents include, for example, apparent security violations or suspicious physical access activities. Suspicious physical access activities include, for example; (I) accesses outside of normal work hours; (ii) repeated accesses to areas not normally accessed; (iii) accesses for unusual lengths of time; and (iv) out-of-sequenc accesses. Related controls: CA-7, IR-4, IR-8.	(1) MONITORING PHYSICAL ACCESS INTRUSION ALARMS / SURVEILLANCE EQUIPMENT The organization monitors physical intrusion alarms and surveillance equipment. (2) MONITORING PHYSICAL ACCESS AUTOMATED INTRUSION RESCONITION / RESPONSES The organization employs automated mechanisms to recognize [Assignment: organization-defined classes/types of intrusions] and initiate [Assignment: organization-defined response actions]. Supplemental Guidance: Related control: S1-4. (3) MONITORING PHYSICAL ACCESS VIDEO SURVEILLANCE The organization employs video surveillance (Assignment: organization-defined period). Supplemental Guidance: This control enhancement focuses on recording surveillance video for purposes of subsequent review, if circumstances so warrant (e.g., a break-in detected by other means). It does not require monitoring surveillance video although organizations may choose to do so. Note that there may be legal considerations when performing and retaining video surveillance, especially if such surveillance is in a public location. (4) MONITORING PHYSICAL ACCESS MONITORING PHYSICAL ACCESS TORNORAMION SYSTEMS. The organization monitors physical access to the information system in addition to the physical access monitoring of the facility as [Assignment: organization-defined physical spaces containing one or more components of the information system). Supplemental Guidance: This control enhancement provides additional monitoring for those areas within facilities where there is a concentration of information system components (e.g., server rooms, media storage areas, communications centers). Related controls: PS-2, PS-3.	None
PE-9 POWER EQUIPMENT AND CABLING	The organization protects power equipment and power cabling for the information system from damage and destruction.	A11.1.4, A11.2.1, A11.2.2, A11.2.3	Organizations determine the types of protection necessary for power equipment and cabling employed at different locations both internal and external to organizational facilities and environments of operation. This includes, for example, generators and power cabling outside of buildings, internal cabling and uninterruptable power sources within an office or data center, and power sources for self-contained entities such as vehicles and satellites. Related control: PE-4.	The organization employs redundant power cabling paths that are physically separated by [Assignment: organization-defined distance]. Supplemental Guidance: Physically separate, redundant power cables help to ensure that power continues to flow in the event one of the cables is cut or otherwise damaged.	None
PE-18 LOCATION OF INFORMATION SYSTEM COMPONENTS	The organization positions information system components within the facility to minimize potential damage from [Assignment: organization-defined physical and environmental hazards] and to minimize the opportunity for unauthorized access.	A8.2.3, A.11.1.4, A.11.2.1	Physical and environmental hazards include, for example, flooding, fire, tornados, earthquakes, hurricanes, acts of terrorism, vandalism, electromagnetic pulse, electrical interference, and other forms of incoming electromagnetic radiation. In addition, organizations consider the location of physical entry points where unauthorized individuals, while not being granted access, might nonetheless be in close proximity to information systems and therefore increase the potential for unauthorized access to organizational communications (e.g., through the use of wireless sniffers or microphones). Related controls: CP-2, PE-19, RA-3.	(1) LOCATION OF INFORMATION SYSTEM COMPONENTS FACILITY SITE The organization plans the location or site of the facility where the information system resides with regard to physical and environmental hazards and for existing facilities, considers the physical and environmental hazards in its risk mitigation strategy. Supplemental Guidance: Related control: PM-8.	None

Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
PL-1 SECURITY PLANNING POLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A security planning policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the security planning policy and associated security planning controls; and b. Reviews and updates the current: 1. Security planning procleures [Assignment: organization-defined frequency]; and 2. Security planning procleures [Assignment: organization-defined frequency].	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A182.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the PL family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizationarisk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
PL-2 SYSTEM SECURITY PLAN	The organization: a. Develops a security plan for the information system that: 1. Is consistent with the organization's enterprise architecture; 2. Explicitly defines the authorization boundary for the system; 3. Describes the operational context of the information system in terms of missions and business processes; 4. Provides the security categorization of the information system including supporting rationale; 5. Describes the operational environment for the information system and relationships with or connections to other information systems; 6. Provides an overview of the security requirements for the system; 7. Identifies any relevant overlays, if applicable; 8. Describes the security controls in place or planned for meeting those requirements including arationale for the tailoring decisions; and 9. Is reviewed and approved by the authorizing official or designated representative prior to plan implementation; b. Distributes copies of the security plan and communicates subsequent changes to the plan to [Assignment: organization-defined personnel or roles]; c. Reviews the security plan for the information system/environment of operation or problems identified during plan implementation or security control assessments; and e-Protects the security in from unauthorized disclosure and modification.	A14.1.1	Security plans relate security requirements to a set of security controls and control enhancements. Security plans also describe, at a high level, how the security controls and control enhancements meet those security requirements but do not provide detailed, technical descriptions of the specific design or implementation of the controls/enhancements. Security plans contain sufficient information (including the specification of parameter values for assignment and selection statements either explicitly or by reference) to enable a design and implementation that is unambiguously compliant with the intent of the plans and subsequent determinations of rish or agnizational operations and assets, individuals, other organizations, and the Nation if the plan is implemented as intended. Organizations can also apply tailoring guidance to the security control baselines in Appendix D and CNSS instruction 1253 to develop overlays for community-wide use or to address specialized requirements, technologies, or missions/environments of operation [e.g. Dol-actical, Pederal Public Key Infrastructure, or Federal Identity, Credential, and Access Management, space operations). Appendix I provides guidance on developing overlays. Security plans need not be single documents; the plans can be a collection of various documents including documents that already exist. Effective security plans make extensive use of references to policies, procedures, and additional documents fire reduces the documentation requirements associated with security programs and maintains security-related information in other established management/operational areas related to enterprise architecture, system development life cycle, systems engineering and acquisition. For example, security pans and on contain detailed contingency plan or incident response plan information but instead provide explicitly or by reference, sufficient information to define what needs to be accomplished by those plans. Related controls: A.C.2, A.C.6, A.C.14, A.C.17, A.C. 20, C.A.2, C	(1) SYSTEM SECURITY PLAN CONCEPT OF OPERATIONS [Withdrawn: incorporated into PL-7]. [Withdrawn: incorporated into PL-7]. [2) SYSTEM SECURITY PLAN FUNCTIONAL ARCHITECTURE [Withdrawn: incorporated into PL-8]. [Withdrawn: incorporated into PL-8]. [3) SYSTEM SECURITY PLAN PLAN / COORDINATE WITH OTHER ORGANIZATIONAL ENTITIES The organization plans and coordinates security-related activities affecting the information system with [Assignment: organization-defined individuals or groups] before conducting such activities in order to reduce the impact on other organization entities. Supplemental Guidance: Security-related activities include, for example, security assessments, audits, hardware and software maintenance, patch management, and contingency plan testing. Advance planning and coordination includes emergency and nonemergency (i.e., planned or nonurgent unplanned) situations. The process defined by organizations to plan and coordinate security-related activities can be included in security plans for information systems or other documents, as appropriate. Related controls: CP-4, IR-4.	None
PL-4 RULES OF BEHAVIOR	The organization: a. Establishes and makes readily available to individuals requiring access to the information system, the rules that describe their responsibilities and expected behavior with regard to information and information system usage; b. Receives a signed acknowledgment from such individuals, indicating that they have read, understand, and agree to abide by the rules of behavior, before authorizing access to information and the information system; c. Reviews and updates the rules of behavior [Assignment: organization-defined frequency]; and d. Requires individuals who have signed a previous version of the rules of behavior to read and re-sign when the rules of behavior are revised/updated.	A7.1.2, A7.2.1, A8.1.3	not feasible given the large number of such users and the limited nature of their interactions with the systems. Rules of behavior for both organizational and non-organizational users can also be established in AC-8, System Use	(1) RULES OF BEHAVIOR SOCIAL MEDIA AND NETWORKING RESTRICTIONS The organization includes in the rules of behavior, explicit restrictions on the use of social media/networking sites and posting organizational information on public websites. Supplemental Guidance: This control enhancement addresses rules of behavior related to the use of social media/networking sites: (i) when organizational personnel are using such sites for official duties or in the conduct of official business; (ii) when organizational information is involved in social media/networking transactions; and (iii) when personnel are accessing social media/networking sites from organizational information systems. Organizational sols address specific rules that prevent unauthorized entities from obtaining and/or inferring non-public organizational information (e.g., system account information, personally identifiable information) from social media/networking sites.	None
PL-7 SECURITY CONCEPT OF OPERATIONS	The organization: a. Develops a security Concept of Operations (CONOPS) for the information system containing at a minimum, how the organization intends to operate the system from the perspective of information security; and b. Reviews and updates the CONOPS [Assignment: organization-defined frequency].	A.14.1.1 (only partially satisfies NIST control)	The security CONOPS may be included in the security plan for the information system or in other system development life cycle-related documents, as appropriate. Changes to the CONOPS are reflected in ongoing updates to the security plan, the information security architecture, and other appropriate organizational documents (e.g., security specifications for procurements/acquisitions, system development life cycle documents, and systems/security engineering documents). Related control: PL-2.	None	None
PL-8 INFORMATION SECURITY ARCHITECTURE	The organization: a. Develops an information security architecture for the information system that: 1. Describes the overall philosophy, requirements, and approach to be taken with regard to protecting the confidentiality, integrity, and availability of organizational information; 2. Describes how the information security architecture is integrated into and supports the enterprise architecture; and 3. Describes any information security assumptions about, and dependencies on, external services; b. Reviews and updates the information security architecture [Assignment organization-defined frequency] to reflect updates in the enterprise architecture; and c. Ensures that planned information security architecture changes are reflected in the security plan, the security Concept of Operations (CONOPS), and organizational procurements/acquisitions.	A.14.1.1 (only partially satisfies NIST control)		(1) INFORMATION SECURITY ARCHITECTURE DEFENSE-IN-DEPTH The organization designs its security architecture using a defense-in-depth approach that: (a) Allocates (Assignment organization designs its security architecture using a defense-in-depth approach that: (a) Allocates (Assignment organization designs its security architecture using a defense-in-depth approach that: (b) Ensures that the allocated security safeguards operate in a coordinated and mutually reinforcing manner. Supplemental Guidance: Organizations strategically allocate security safeguards (procedural, technical, or both) in the security architecture so that adversaries have to overcome multiple safeguards to achieve their objective. Requiring adversaries to defeat multiple mechanisms makes it more difficult to successfully attack critical information resources (i.e., increases adversary work factor) and also increases the likelihood of detection. The coordination of allocated safeguards is essential to ensure that an attack that involves one safeguard does not create adverse unintended consequences (e.g., lockout, cascading alarms) by interfering with another safeguard. Placement of security safeguards is a key activity. Oreater asset criticality or information value merits additional layering. Thus, an organization may choose to place anti-virus software at organizational boundary layers, email/web servers, notebook computers, and workstations to maximize the number of related safeguards adversaries must penetrate before compromising the information and information systems. Related controls: SC-29, SC-36. (2) INFORMATION SECURITY ARCHITECTURE SUPPLIER DIVERSITY The organization requires that [Assignment: organization-defined security safeguards] allocated to [Assignment: organization and architectural layers] are obtained from different suppliers. Supplemental Guidance: Different information technology products are different strengths and weaknesses. Providing a broad spectrum of products complements the individual offerings. For example,	None
PM-1 INFORMATION SECURITY PROGRAM PLAN	The organization: a. Develops and disseminates an organization-wide information security program plan that: 1. Provides an overview of the requirements for the security program and a description of the security program management controls and common controls in place or planned for meeting those requirements; 2. Includes the identification and assignment of roles, responsibilities, management commitment, coordination among organizational entities, rand compliance; 3. Reflects coordination among organizational entities responsibilities, and compliance; 3. Reflects coordination among organizational entities responsibility and accountability for the risk being incurred to organizational operations (including mission, functions, image, and reputation), organizational assets, individuals, other organizations, and the Nation; b. Reviews the organization-wheel information security program plan [Assignment: organization-defined frequency]; c. Updates the plan to address organizational changes and problems identified during plan implementation or security control assessments; and d. Protects the information security program plan from unauthorized disclosure and modification.	A5.1.1, A5.1.2, A6.1.1, A18.1.1, A.18.2.2	Information security program plans can be represented in single documents or compilations of documents at the discretion of organizations. The plans document the program management controls and organization-defined common controls. Information security program plans provide sufficient information about the program management controls /common controls (and duffing specification) of parameters for any assignment and selection statements either explicitly or by reference) to enable implementations that are unambiguously compilant with the intent of the plans and a determination of the risk to be incurred if the plans are implemented as intended. The security plans for individual information systems and the organization-wide information security program plan unless the controls are documented in an appendix to the organization's information security program plan unless the controls are included in a separate security plan for an information system (e.g. security controls employed as part of an intrusion detection system providing organization-wide boundary protection inherited by one or more organizational information systems). The organization-wide information security program plan will indicate which separate security plans contain descriptions of common controls. Organizations have the flexibility to describe common controls in a single document or in multiple documents. In the case of multiple documents, the documents describing common controls are included as attachments to the information security program plan. If the information security program plan contains multiple documents, the organization appecifies in each document the organization official or officials responsible for the development, implementation, assessment, authorization, and monitoring of the respective common controls. For example, the organization and many require that the Facilities Management Office develop, implement, assess, authorize, and continuously monitor common physical and environmental protection controls from the PE family when	None e	None
PM-9 RISK MANAGEMENT STRATEGY	The organization: a. Develops a comprehensive strategy to manage risk to organizational operations and assets, individuals, other organizations, and the Nation associated with the operation and use of information systems; b. Implements the risk management strategy consistently across the organization; and c. Reviews and updates the risk management strategy [Assignment: organization-defined frequency] or as required, to address organizational changes.	None	An organization-wide risk management strategy includes, for example, an unambiguous expression of the risk tolerance for the organization, acceptable risk assessment methodologies, risk mitigation strategies, a process for consistently evaluating risk across the organization with respect to the organization's risk tolerance, and approaches for monitoring risk over time. The use of a risk executive function can facilitate consistent, organization-wide application of the risk management strategy. The organization-wide risk management strategy can be informed by risk-related injust from other sources both internal and external to the organization to ensure the strategy is both broad-based and comprehensive. Related control: RA-3.	- None	None

Tab: Controls and Guidance

Doc Number: D000003422 Name: Product security standard assessment Revision: AB

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Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
PM-12 INSIDER THREAT PROGRAM	The organization implements an insider threat program that includes a cross-discipline insider threat incident handling team.	None	Organizations handling classified information are required, under Executive Order 13587 and the National Policy or Insider Prinary, to establish insider threat programs. The standards and guidelines that apply to insider threat programs in classified environments can also be employed effectively to improve the security of Controlled Unclassified Information in non-national security systems. Insider threat programs include security controls to detect and prevent malicious insider activity through the centralized integration and analysis of both technical and non-technical information to identify potential insider threat concerns. A senior organizational official is designated by the department/agency head as the responsible individual to implement and provide oversight for the program. In addition to the centralized integration and analysis capability, insider threat programs as a minimum, prepare department/agency insider threat policies and implementation plans, conduct host-based user monitoring of individual employees, receive access to information from all offices within the department/agency (e.g., human resources, legal, physical security, personnel security, information technology, information system security, and law enforcement plor insider threat analysis, and conduct self-assessments of department/agency insider threat posture. Insider threat programs can leverage the existence of incident handling teams organizations may already have in place, such as computer security incident response teams. Human resources records are especially important in this effort, as there is compelling evidence to show that some types of inafer crimes are often preceded by nontechnical behaviors in the workplace (e.g., ongoing patterns of disgruntled behavior and conflicts with toworkers and other colleagues). These precursors can better inform and guide organizational officials in more focused, targeted monitoring efforts. The participation of a legal team is important to ensure that all monitoring activities are perfor	v None s	None
PM-14 TESTING, TRAINING, AND MONITORING	The organization: a. Implements a process for ensuring that organizational plans for conducting security testing, training, and monitoring activities associated with organizational information systems: 1. Are developed and maintained; and 2. Continue to be executed in a timely manner; b. Reviews testing training, and monitoring plans for consistency with the organizational risk management strategy and organization-wide priorities for risk response actions.	None	conducted organization-wide and that those activities are coordinated. With the importance of continuous monitoring programs, the implementation of information security across the three tiers of the risk management hierarchy, and the widespread use of common controls, organizations coordinate and consolidate the testing and monitoring activities that are routinely conducted as part of ongoing organizational assessments supporting a variety of security controls. Security training activities, while typically focused on individual information systems and specific roles, also necessitate coordination across all organizational elements. Testing, training, and monitorin plans and activities are informed by current threat and vulnerability assessments. Related controls: AT-3, CA-7, CP-4, IR-3, SI-4.	None g	None
PM-15 CONTACTS WITH SECURITY GROUPS AND ASSOCIATIONS	The organization establishes and institutionalizes contact with selected groups and associations within the security community: a. To facilitate ongoing security education and training for organizational personnel; b. To maintain currency with recommended security practices, techniques, and technologies; and c. To share current security-related information including threats, vulnerabilities, and incidents.	A6.1.4	Ongoing contact with security groups and associations is of paramount importance in an environment of rapidly changing technologies and threats. Security groups and associations include, for example, special interest groups, forums, professional associations, news groups, and/or peer groups of security professionals in similar organizations. Organizations select groups and associations based on organizational missions/business functions. Organizations select groups and associations based on organizational missions/business functions. Organizations share threat, vulnerability, and incident information consistent with applicable federal laws, Executive Orders, directives, policies, regulations, standards, and guidance. Related control: SI-5.	None	None
PM-16 THREAT AWARENESS PROGRAM	The organization implements a threat awareness program that includes a cross-organization information-sharing capability.	None	Because of the constantly changing and increasing sophistication of adversaries, especially the advanced persistent threat (APT), it is becoming more likely that adversaries may successfully breach or compromise organizational information systems. One of the best techniques to address this concern is for organizations to share threat information. This can include, for example, sharing threat events (i.e., tactics, techniques, and procedures) that organizations have experienced, mitigations that organizations have found are effective against certain types of threats, threat intelligence (i.e., indications and warnings about threats that are likely to occur). Threat information sharing may be bilateral (e.g., government-commercial cooperatives, overnment-government cooperatives), or multilateral (e.g., organizations taking part in threat-sharing consortia). Threat information may be highly sensitive requiring special agreements and protection, or less sensitive and freely shared. Related controls: PM-12, PM-16.		None
PS-1 PERSONNEL SECURITY POLICY AND PROCEDURES	The organization: a Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A personnel security policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the personnel security policy and associated personnel security controls; and b. Reviews and updates the current: 1. Personnel security policy [Assignment: organization-defined frequency]; and 2. Personnel security procedures [Assignment: organization-defined frequency].	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A18.2.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the PS family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizationarisk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
RA-5 VULNERABILITY SCANNING	The organization: a. Scans for vulnerabilities in the information system and hosted applications [Assignment: organization-defined frequency and/or randomly in accordance with organization-defined process] and when new vulnerabilities potentially affecting the system/applications are identified and reported; b. Employs vulnerability scanning tools and techniques that facilitate interoperability among tools and automate parts of the vulnerability management process by using standards for: 1. Enumerating platforms, software flaws, and improper configurations; 2. Formatting checklists and test procedures; and 3. Measuring ulnerability mpact; c. Analyzes vulnerability scan reports and results from security control assessments; d. Remediates legitimate vulnerabilities [Assignment: organization-defined response times] in accordance with an organizational assessment of risk; and e. Shares information obtained from the vulnerability scanning process and security control assessments with [Assignment: organization-defined personnel or roles] to help eliminate similar vulnerabilities in other information systems (i.e., systemic weaknesses or deficiencies).	A.12.6.1 (only partially satisfies NIST control)	use the Open Vulnerability Assessment Language (OVAL) to determine/test for the presence of vulnerabilities. Suggested sources for vulnerability information include the Common Weakness Enumeration (CWE) listing and the National Vulnerability Database (NVD). In addition, security control assessments such as red team exercises provide other sources of potential vulnerabilities for which to scan. Organizations also consider using tools that express	The organization employs vulnerability scanning procedures that can identify the breadth and depth of coverage (i.e., information system components scanned and vulnerabilities checked). (4) VULNERABILITY SCANNING DISCOVERABLE INFORMATION The organization determines what information about the information system is discoverable by adversaries and subsequently takes [Assignment: organization-defined corrective actions]. Supplemental Guidance: Discoverable information includes information that adversaries could obtain without directly compromising or breaching the information system, for example, by collecting information the system is exposing or by conducting extensive searches of the web. Corrective actions can include, for example, notifying appropriate organizational personnel, removing designated information, or changing the information system to make designated information less relevant or attractive to adversaries. Related control: AU-13. (5) VULNERABILITY SCANNING PRIVILEGED ACCESS The information system implements privileged access authorization to [Assignment: organization-identified information system components] for selected [Assignment: organization-defined vulnerability scanning activities]. Supplemental Guidance: In certain situations, the nature of the vulnerability scanning may be more intrusive or the information system component that is the subject of the scanning may contain highly sensitive information. Privileged access authorization to selected system components facilitates more through vulnerability scanning ads protects the sensitive nature of sub-scanning may contain highly sensitive information.	None
SA-1 SYSTEM AND SERVICES ACQUISITION POLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A system and services acquisition policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the system and services acquisition policy and associated system and services acquisition controls; and b. Reviews and updates the current: 1. System and services acquisition policy [Assignment: organization-defined frequency]; and 2. System and services acquisition procedures [Assignment: organization-defined frequency].	A5.1.1,A5.1.2,A61.1,A12.1.1,A18.1.1, A182.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the SA family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizationarisk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.	None	None
SA:3 SYSTEM DEVELOPMENT LIFE CYCLE	The organization: a. Manages the information system using [Assignment: organization-defined system development life cycle] that incorporates information security considerations; b. Defines and documents information security roles and responsibilities throughout the system development life cycle; c. Identifies individuals having information security roles and responsibilities; and d. Integrates the organizational information security risk management process into system development life cycle activities.	A61.1, A61.5, A141.1, A142.1, A142.6	A well-defined system development life cycle provides the foundation for the successful development, implementation, and operation of organizational information systems. To apply the required security controls within the system development life cycle requires a basic understanding of information security, threats, vulnerabilities, adverse impacts, and risk to critical missions/business functions. The security engineering principle in SA-8 cannot be properly applied if individuals that design, code, and test information systems and system components (including information system for example, chief information security officers, security engineers, and information system security officers in system development life cycle activities to ensure that security requirements are incorporated into organizational information systems. It is equally important that developers include individuals on the development team that possess the requisite security expertise and skills to ensure that needed security capabilities are effectively integrated into the information systems. Security awareness and training programs can help ensure that individuals having key security roles and responsibilities have the appropriate experience, skills, and expertise to conduct assigned system development life cycle activities. The effective integration of security requirements into enterprise architecture also helps to ensure that important security considerations are addressed early in the system development life cycle and that those considerations are directly related to the organizational mission flusiness processes. This process also facilitates the integration of the information security architecture into the enterprise architecture, consistent with organizational risk management and information security architecture into the enterprise architecture, consistent with organizational risk management and information security architecture into the enterprise architecture, consistent with organizational risk management and information security a	None	None



	a . 10 . 15 . (There 50 . 1)	ISO/IEC 27001 Controls that fulfill	5 1 15 15 (55 55 55 1)		
Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
SA-4 ACQUISITION PROCESS	The organization includes the following requirements, descriptions, and criteria, explicitly or by reference, in the acquisition contract for the information system, system component, or information system service in accordance with applicable federal laws, Executive Orders, directives, policies, regulations, standards, guidelines, and organizational mission/business needs: a. Security functional requirements; b. Security strength requirements; c. Security susurance requirements; d. Security-related documentation requirements; e. Requirements for protecting security-related documentation; f. Description of the information system development environment and environment in which the system is intended to operate; and g. Acceptance criteria.	A.14.1.1, A.14.2.7, A.14.2.9, A.15.1.2	to tampering or bypass. Security assurance requirements include: [i) development processes, procedures, practices and methodologies and (ii) evidence from development and assessment activities providing grounds for confidence that the required security functionality has been implemented and the required security strength has been achieved Security documentation requirements address all phases of the system development life cycle. Security functionality, assurance, and documentation requirements are expressed in terms of security controls and control enhancements that have been selected through the tailoring process. The security control tailoring process includes, for example, the specification of parameter values through the use of assignment and selection statements and the specification of platform dependencies and implementation information. Security documentation provides user and administrator guidance regarding the implementation and operation of security controls. The level of detail required in security documentation is based on the security category or classification level of the information system and the degree to which organizations depend on the stated security capability, functions, or mechanisms to meet overall risk response expectations (sa defined in the organizational risk management strategy). Security	Supplemental Guidance: Organizations may require different levels of detail in design and implementation documentation for security controls employed in organizational information systems, system components, or information system services based on mission/business requirements, requirements for trustworthiness/resiliency, and requirements for analysis and testing, Information systems, can be partitioned into multiple subsystems within the system can contain one or more modules. The high-level design for the system is expressed in terms of multiple subsystems and the interfaces between subsystems providing security-relevant functionality. Oscure code and hardware schematics are typically referred to as the implementation requires the developer of the information system. Related control: SA-5. [3] ACQUISTION PROCESS DEVELOPMENT METHODS / TECHNIQUES / PRACTICES The organization requires the developer of the information system, system component, or information system service to demonstrate the use of a system development life cycle that includes [Assignment: organization-defined state-of-the-practice system/security engineering methods, software development methods, testing/evaluation/validation techniques, and quality control processes]. Supplemental Guidance: Following a well-defined system development life cycle that includes (assignment: organization-defined state-of-the-practice software development methods, systems/security engineering methods, quality control processes, and testing, evaluation, and validation techniques helps to reduce the number and severity of state errors within information systems, system components, and information system services. Reducing the number/severity of such errors reduces the number of vulnerabilities in those systems, components, and services. Related control: SA-12. (4) ACQUISTION PROCESS SISSIGNMENT OF COMPONENTS TO SYSTEMS (SOMPONENTS TO SYSTEMS (SOMPONENTS T) SYSTEM / (SOMPONENTS T) SYSTEM / (SOMPONENTS T) SYSTEM / (SOMPONENTS T) SERVICE CONFIGURATIONS (S) A	None
SA-5 INFORMATION SYSTEM DOCUMENTATION	The organization: a. Obtains administrator documentation for the information system, system component, or information system service that describes: 1. Secure configuration, installation, and operation of the system, component, or service; 2. Effective use and maintenance of security functions/mechanisms; and 3. Known vulnerabilities regarding configuration and use of administrative (i.e., privileged) functions; b. Obtains user documentation for the information system, system component, or information system service that describes: 1. User-accessible security functions/mechanisms and how to effectively use those security functions/mechanisms; 2. Methods for user interaction, which enables individuals to use the system, component, or service in a more secure manner; and 3. User responsibilities in maintaining the security of the system, component, or service; c. Documents attempts to obtain information system, system component, or information system service documentation when such documentation is either unavailable or nonexistent and takes [Assignment: organization-defined actions] in response; d. Protects documentation as required, in accordance with the risk management strategy; and e. Distributes documentation of classignment: organization-defined personnel or roles].	A.12.1.1 (only partially satisfies NIST control)	This control helps organizational personnel understand the implementation and operation of security controls associated with information systems, system components, and information system services. Organizations consider establishing specific measures to determine the quality/completeness of the content provided. The inability to obtain needed documentation may occur, for example, due to the age of the information system/component or lack of support from developers and contractors. In those situations, organizations may need to recreate selected documentation if such documentation is essential to the effective implementation or operation of security controls. The level of protection provided for selected information system, component, or service documentation is commensurate with the security category or classification of the system. For example, documentation secondary with a key DoD weapons system or command and control system would typically require a higher level of protection than a routine administrative system. Documentation that addresses information system vulnerabilities may also require an increased level of protection. Secure operation of the information system, includes, for example initially starting the system and resuming secure system operation after any lapse in system operation. Related controls: CM-6, CM-8, PL-2, PL-4, PS-2, SA-3, SA-4.	(1) INFORMATION SYSTEM DOCUMENTATION FUNCTIONAL PROPERTIES OF SECURITY CONTROLS [Withdrawn: Incorporated into SA-4 (1)]. (2) INFORMATION SYSTEM DOCUMENTATION SECURITY-RELEVANT EXTERNAL SYSTEM INTERFACES [Withdrawn: Incorporated into SA-4 (2)]. (Withdrawn: Incorporated into SA-4 (2)]. (4) INFORMATION SYSTEM DOCUMENTATION HIGH-LEVEL DESIGN [Withdrawn: Incorporated into SA-4 (2)]. (4) INFORMATION SYSTEM DOCUMENTATION LOW-LEVEL DESIGN [Withdrawn: Incorporated into SA-4 (2)].	None
SA-8 SECURITY ENGINEERING PRINCIPLES	The organization applies information system security engineering principles in the specification, design, development, implementation, and modification of the information system.	A.14.2.5	Organizations apply security engineering principles primarily to new development information systems or systems undergoing major upgrades. For legacy systems, organizations apply security engineering principles to system upgrades and modifications to the extent feasible, given the current state of hardware, software, and firmware within those systems. Security engineering principles include, for example: (i) developing layered protections; (ii) establishing sound security policy, architecture, and controls as the foundation for design; (iii) incorporating security requirements into the system development life cycle; (iv) delineating physical and logical security boundaries; (v) ensuring that system developers are trained on how to build secure software; (vi) tailoring security controls to meet organizational and operational needs; (vii) performing threat modeling to identify use cases, threat agents, attack vectors, and attack patterns as well as compensating controls and design patterns needed to mitigate risk; and (viii) reducing risk to acceptable levels, thus enabling informed risk management decisions. Related controls: PM-7, SA-3, SA-4, ST-1, SC-2, SC-3		None
SA-9 EXTERNAL INFORMATION SYSTEM SERVICES	The organization: a. Requires that providers of external information system services comply with organizational information security requirements and employ [Assignment: organization-defined security controls] in accordance with applicable federal laws, Executive Orders, directives, policies, regulations, standards, and guidance; b. Defines and documents government oversight and user roles and responsibilities with regard to external information system services; and c. Employs [Assignment: organization-defined processes, methods, and techniques] to monitor security control compliance by external service providers on an ongoing basis.	A6.1.1, A6.1.5, A7.2.1, A13.1.2, A.13.2.2, A15.2.1, A15.2.2	External information system services are services that are implemented outside of the authorization boundaries of organizational information systems. This includes services that are used by, but not a part of, organizational information systems. This may do MOB polity require that organizations using external service providers that are processing, storing, or transmitting federal information or operating information systems on behalf of the federal government ensure that such providers ment the same security requirements that federal agencies are required to meet. Organizations establish relationships with external service providers in a variety of ways including, for example, through joint ventures, business partnerships, contracts, interagency agreements, lines of business arrangements, licensing agreements, and supply chain exchanges. The responsibility for managing risks from the us of external information system services remains with authorizing officials. For services external to organizations, as chain of rust varies based on the relationships between organizations and the extent providers. Organizations adocument the basis for trust relationships between organizations and the external providers. Organizations document the basis for trust relationships can be monitored over time External information system services documentation includes government, service providers, end user security roles and responsibilities, and service-level agreements. Service-level agreements define expectations of performance for security controls, describe measurable outcomes, and identify remedies and response requirements for identified instances of noncompliance. Related controls: CA-3, IR-7, PS-7.	[1] EXTERNAL INFORMATION SYSTEMS [ISIN ASSESSMENTS / ORGANIZATIONAL APPROVALS [2] EXTERNAL INFORMATION SYSTEMS [ISIN ASSESSMENTS / ORGANIZATIONAL APPROVALS [3] Conducts an organizational assessment of risk prior to the acquisition or outsourcing of dedicated information security services is approved by [Assignment: organization-defined personnel or roles]. Supplemental Guidance: Dedicated information security services include, for example, incident monitoring, analysis and response, operation of information security-related devices such as firewalls, or key management services. Pacided controls: C.4-6, RA-3. [2] EXTERNAL INFORMATION SYSTEMS [IDENTIFICATION OF FUNCTIONS / PORTS / PROTOCOLS / SERVICES. The organization requires providers of [Assignment organization-defined external information system services] to identify the functions, ports, protocols, and other services required for the use of such services. Supplemental Guidance: Information from external service providers regarding the specific functions, ports, protocols, and services used in the provision of such services can be particularly useful when the need arises to understand the trade-offs involved in restricting certain functions/services or blocking oretain ports/protocols. Related control. M-7. [3] EXTERNAL INFORMATION SYSTEMS [ESTABLISH / MAINTAIN TRUST RELATIONSHIP WITH PROVIDERS The organization establishes, documents, and maintains trust relationships with external service is at an acceptable level depends on the trust that organization place in the external providers, individually or in combination. Trust relationships can be plo organization to gain increased levels of confidence that participating service providers are providing adequate protection for the services rendered. Such relationships can be complicated due to the number of potential entities participating in the consumer-provider interactions, subvotent and the types of interactions between the particies. Insome cases, the degree of trust is hased on the trade of t	None



Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
SA-10 DEVELOPER CONFIGURATION MANAGEMENT	The organization requires the developer of the information system, system component, or information system service to: a. Perform configuration management during system, component, or service [Selection (one or more): design; development; implementation, operation]: b. Document, manage, and control the integrity of changes to [Assignment: organization-defined configuration items under configuration management]: c. Implement only organization-approved changes to the system, component, or service; d. Document approved changes to the system, component, or service and the potential security impacts of such changes; and e. Track security flaws and flaw resolution within the system, component, or service and report findings to [Assignment: organization-defined personnel].	A12.12, A14.22, A14.2.4, A14.2.7	This control also applies to organizations conducting internal information systems development and integration. Organizations consider the quality and completeness of the configuration management activities conducted by developers as evidence of applying effective security safeguards. Safeguards include, for example, protecting from unauthorized modification or destruction, the master copies of all material used to generate security-relevant portions of the system hardware, software, and firmware. Maintaining the integrity of changes to the information system, information system component, or information system service requires configuration control throughout the system development life cycle to track authorized changes and prevent unauthorized changes. Configuration items that are placed under configuration management (if existence/use is required by other security controls) include: the formal model; the functional, high-level, and low-level design specifications; other design data; implementation documentation; source code and hardware schematics, the running version of the object code; tool for comparing new versions of security-relevant hardware descriptions and software/firmware source code with previous versions; and test fixtures and documentation. Depending on the mission/business needs of organization and the nature of the contractual relationships in place, developers may provide configuration management suppor during the operations and maintenance phases of the life cycle. Related controls: CM-3, CM-4, CM-9, SA-12, SI-2.	The organization requires the developer of the information system, system components, or information system service to enable integrity verification of hardware components. Supplemental Guidance: This control enhancement allows organizations to detect unauthorized changes to hardware components through the use of tools, techniques, and/or mechanisms provided by developers. Organizations verify the integrity of hardware components, for example, with hard-to-copy labels and verifiable serial numbers provided by developers, and by requiring the implementation of anti-tamper technologies. Delivered hardware components also include updates to such components. Related control: SI-7. (4) DEVELOPER CONFIGURATION MANAGEMENT TRUSTED GENERATION The organization requires the developer of the information system, system component, or information system service to employ tools for comparing newly generated versions of security-relevant hardware descriptions and is software, firmware source and object code with previous Supplemental Guidance: This control enhancement addresses changes to hardware, software, and firmware components between versions during development. In contrast, SA-10 (1) and SA-10 (3) allow organizations to sedected unauthorized changes to hardware, software, and firmware components between versions during development. In contrast, SA-10 (1) and SA-10 (3) allow organizations to sedected unauthorized changes to hardware, software, and firmware components provided by developers. It (5) DEVELOPER CONFIGURATION MANAGEMENT MAPPING INTEGRITY FOR VERSION CONTROL The organization requires the developer of the information system, system component, or information system service to maintain the integrity of the mapping between the master build data (hardware drawings and software/firmware code) describing the current version of security-relevant hardware, software, and firmware and the on-site master copies on-site in operational environments is essential to ensure the availability of organizational informatio	None
SA-11 DEVELOPER SECURITY TESTING AND EVALUATION	The organization requires the developer of the information system, system component, or information system service to: a. Create and implement a security assessment plan; b. Perform [Selection (one or more): unit; integration; system; regression] testing/evaluation at [Assignment organization-defined depth and coverage]; c. Produce evidence of the execution of the security assessment plan and the results of the security testing/evaluation; d. Implement a verifiable flaw remediation process; and e. Correct flaws identified during security testing/evaluation.	t A142.7, A142.8	Developmental security testing/evaluation occurs at all post-design phases of the system development life cycle. Such testing/evaluation confirms that the required security controls are implemented correctly, operating as intended, enforcing the desired security policy, and meeting established security requirements. Security properties of information systems may be affected by the interconnection of system components or changes to those components. These interconnections or changes (e.g., upgrading or replacing applications and operating systems) may adversely affect previously implemented security controls. This control provides additional types of security testing/evaluation that developers can conduct to reduce or eliminate potential flaws. Testing custom software applications may require approaches such as static analysis, dynamic analysis, binary analysis, or a hybrid of the three approaches. Developers can employ these analysis approaches in a variety of tools (e.g., web-based applications scanners, static analysis tools, binary analyzers) and in source code reviews. Security assessment plans provide the specific activities that developers plan to carry out including the types of analyses, testing, evaluation, and reviews of software and firmware components, the degree of rigor to be applied, and the types of artifacts produced during those processes. The depth of security testing/evaluation refers to the rigor and level of detail associated with the assessment process (e.g., black box, gray box, or white box testing). The coverage of security testing/evaluation refers to the scope (i.e., number and type) of the artifacts included in the assessment process. Contracts specify the acceptanten criteria for security assessment plans, flav remediation processes, and the evidence that the plans/processes have been diligently applied. Methods for reviewing and protecting assessment plans, evidence, and documentation are commensurate with the security category or classification level of the information system. Co	[1] DEVELOPER SECURITY TESTING AND EVALUATION STATIC CODE ANALYSIS The organization requires the developer of the information system, system component, or information system service to employ static code analysis tools to identify common flaws and document the results of the analysis. Supplemental Guidance: Static code analysis provides a technology and methodology for security reviews. Such analysis can be used to identify security vulnerabilities and enforce security coding practices. Static code analysis is most effective when used early in the development process, when each code change can be automatically scanned for potential weaknesses. Static analysis can provide clear remediation guidance along with defects to enable developers to fits such defects. Evidence of correct implementation of static analysis can include, for example, aggregate defect density for critical defect types, evidence that defects were inspected by developers or security professionals, and evidence that defects were fixed. An excessively high density of ignored infinings (commonly referred to as ignored or false positives) indicates a potential problem with the analysis process or tool. In such cases, organizations weigh the validity of the evidence against evidence from other sources. 2) DEVELOPER SECURITY TESTING AND EVALUATION TIREAET AND VULNERSBIALTY ANALYSES The organization requires the developer of the information system, system component, or service. 3 Supplemental Guidance: Applications may deviate significantly from the functional and design specifications created during the requirements and design phases of the system development life cycle. Therefore, threat and vulnerability analyses of information systems, system components, and services. There and vulnerability analyses of information systems, system components, and services. Threat and vulnerability analyses of the formation system system components and services to perform the authority of the circle as a result of those changes have been reviewed and mitigat	None
SA-12 SUPPLY CHAIN PROTECTION	The organization protects against supply chain threats to the information system, system component, or information system service by employing [Assignment: organization-defined security safeguards] as part of a comprehensive, defense-in-breadth information security strategy.	A14.2.7, A15.1.1, A15.1.2, A15.1.3	vulnerabilities at each phase of the life cycle and the use of complementary, mutually reinforcing strategies to respond to risk. Organizations consider implementing a standardized process to address supply chain risk with respect to information systems and system components, and to educate the acquisition workforce on threats, risk, and required security controls. Organizations use the acquisition/procurement processes to require supply chain entities to implement necessary security safeguards to: (1) reduce the likelihood of unauthorized modifications at each stage in the supply chain, and (ii) protect information systems and information system eservices. Security safeguards include, for example: (1) security controls for development systems, development facilities, and external connections to development systems; (ii) vetting development personnel; and (iii) use of tamper-evident packagin during shipping/warehousing, Methods for reviewing and protecting development plans, evidence, and documentation are commensurate with the security category or classification level of the information systems.	(6) DEVELOPER SECURITY TESTING AND EVALUATION ACTUSINES ACE REVIEWS: (1) SUPPLY CHAIN PROTECTION ACQUISITION STRATEGIES / TOOLS / METHODS The organization employs [Assignment: organization-defined tailored acquisition strategies, contract tools, and procurement methods] for the purchase of the information system, system component, or information system service from suppliers. [6] Supplemental Guidance: The use of acquisition and procurement processes by organizations early in the system development life cycle provides an important vehicle to protect the supply chain. Organizations use available all-source intelligence analysis to inform the tailoring of acquisition strategies, tools, and methods. There are a number of different tools and techniques available (e.g., obscuring the end use of an information system or system component, using blind or filtered buys). Organizations also consider creating incentives for suppliers who: (i) implement required security safeguards; (ii) promote transparency into their organizational processes and security practices; (iii) provide additional vetting of the processes and security practices of subordinate suppliers, critical information system components, and services; (iv) restrict purchases from specific suppliers or countries; and (v) provide contract language regarding the prohibition of tainted or counterfeit components. In addition, organizations can use trusted (/outrolled distribution, delivery, and warehousing options to reduce supply chain risk (e.g., opportunities for adversaries to corrupt information system components or products. Finally, organizations can use trusted (/outrolled distribution, delivery, and warehousing options to reduce supply chain risk (e.g.,	None



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SA-13 TRUSTWORTHINESS	The organization: a. Describes the trustworthiness required in the [Assignment: organization-defined informatior system, information system component, or information system service] supporting its critical missions/business functions; and b. Implements [Assignment: organization-defined assurance overlay] to achieve such trustworthiness.		This control helps organizations to make explicit trustworthiness decisions when designing, developing, and implementing information systems that are needed to conduct critical organizational missions/business functions. Trustworthiness is a characteristic/property of an information system that expresses the degree to which the system can be expected to preserve the confidentiality, integrity, and availability of the information it processes, stores, or transmits. Trustworthy information systems are systems that are capable of being trusted to operate within defined levels of risk despite the environmental disruptions, human errors, and purposeful attacks that are expected to occur in the specified environments of operation. Trustworthy systems are important to mission/pusiness success. Two factors affecting the trustworthiness of information systems include: (i) security functionality (i.e., the security features, functions, and/or mechanisms employed within the system and its environment of operation); and (ii) security assurance (i.e., the grounds for confidence that the security motionality is effective in its application). J. D evelopers, implementers, operators, and maintainers of organizational information systems can increase the level of assurance (and trustworthiness), for example, by employing well-defined security policy models, structured and rigorous hardware, software, and firmware development techniques, sound system/security engineering principles, and secure configuration settings (defined by a set of assurance-related security controls in Appendix EJ. Assurance is also based on the assessment of evidence produced during the system development life cycle. Critical missions/business functions are supported by high-impact systems and the associated assurance requirements for such systems. The additional assurance controls in Table E-4 in Appendix E (designated as optional) can be used to develop and implement high-assurance solutions for specific information systems and system components such i		None
SA-14 CRITICALITY ANALYSIS	The organization identifies critical information system components and functions by performing a criticality analysis for [Assignment: organization-defined information system components, or information system services] at [Assignment: organization defined decision points in the system development life cycle].	. None	Criticality analysis is a key tenet of supply chain risk management and informs the prioritization of supply chain protection activities such as attack surface reduction, use of all-source intelligence, and tailored acquisition strategies. Information system engineers can conduct an end-to-end functional decomposition of an information system to identify mission-critical functions and components. The functional decomposition into the specific functions to perform those missions, and traceability to the hardware, software, and firmware components that implement those functions, including when the functions are shared by many components within and beyond the information system boundary. Information system components that allow for unmediated access to critical components or functions are considered critical due to the inherent vulnerabilities such components create. Criticality is assessed in terms of the impact of the function or component failure on the ability of the component to complete the organizational missions supported by the information system. A criticality analysis is performed whenever an architecture or design is being developed or modified, including upgrades. Related controls: CP-2, PL-2, PL-8, PM-1, S-A-8, S-A-12, S-A-15, A-5, A-20.	(1) CRITICALITY ANALYSIS CRITICAL COMPONENTS WITH NO VIABLE ALTERNATIVE SOURCING [Withdrawn: Incorporated into SA-20].	None
SA-15 DEVELOPMENT PROCESS, STANDARDS, AND TOOLS	The organization: a. Requires the developer of the information system, system component, or information system service to follow a documented development process that: 1. Explicitly addresses security requirements; 2. Identifies the standards and tools used in the development process; 3. Documents the specific tool options and tool configurations used in the development process and 4. Documents, manages, and ensures the integrity of changes to the process and/or tools used in development; and b. Reviews the development process, standards, tools, and tool options/configurations [Assignment: organization-defined frequency] to determine if the process, standards, tools, and tool options/configurations selected and employed can satisfy [Assignment: organization-defined security requirements].	5; A6.1.5, A14.2.1	Development tools include, for example, programming languages and computer-aided design (CAD) systems. Reviews of development processes can include, for example, the use of maturity models to determine the potential effectiveness of such processes. Maintaining the integrity of changes to tools and processes enables accurate supply		None
SA-16 DEVELOPER-PROVIDED TRAINING	The organization requires the developer of the information system, system component, or information system service to provide [Assignment organization-defined training] on the correct use and operation of the implemented security functions, controls, and/or mechanisms.	None	This control applies to external and internal (in-house) developers. Training of personnel is an essential element to ensure the effectiveness of security controls implemented within organizational information systems. Training options include, for example, classroom-style training, web-based /computer-based training, and hands-on training, Organizations can also request sufficient training materials from developers to conduct in-house training or offer self-training to organizational personnel. Organizations developers to conduct training necessary and may require different types of training for different security functions, controls, or mechanisms. Related controls: AT-2, AT-3, SA-5.	None	None
SA-17 DEVELOPER SECURITY ARCHITECTURE AND DESIGN	The organization requires the developer of the information system, system component, or information system service to produce a design specification and security architecture that: a. Is consistent with and supportive of the organization's security architecture which is established within and is an integrated part of the organization's enterprise architecture; b. Accurately and completely describes the required security functionality, and the allocation of security controls among physical and logical components; and c. Expresses how individual security functions, mechanisms, and services work together to provide required security capabilities and a unified approach to protection.	. A.14.2.1, A.14.2.5	This control is primarily directed at external developers, although it could also be used for internal (in-house) development. In contrast, PL-B is primarily directed at internal developers to help ensure that organizations develop an information security architecture is integrated or tightly coupled to the enterprise architecture. This distinction is important if/when organizations outsource the development of information systems, information systems, information systems services to external entities, and there is a requirement to demonstrate consistency with the organization's enterprise architecture and information security architecture. Related controls: PL-B, PM-7, SA-3, SA-B.	(a) Produce, as an integral part of the development process, a formal policy model describing the [Assignment: organization defined elements of organizational security policy] to be enforced; and the organization requires the development process, a formal policy model describing the [Assignment: organization defined elements of organizational security policy] to be enforced; and to provide a security product of the development process, a formal policy model describes specific behaviors or security policies to the force the defined elements of the organizational security policy when implemented. Supplemental Guidance: Formal models describe specific behaviors or security policies to specific behaviors or security on specific behaviors or specific behaviors or security on policies to the formal provided of the information systems can be modeled, and generally, formal specifications are scoped to specific behaviors or policies of the formal provided provided and provided provided provided by the provided pro	None



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iA-18 AMPER RESISTANCE AND DETECTION	The organization implements a tamper protection program for the information system, system component, or information system service.		Anti-tamper technologies and techniques provide a level of protection for critical information systems, system components, and information technology products against a number of related threats including modification, reverse engineering, and substitution. Strong identification combined with tamper resistance and/or tamper detection is essential to protecting information systems, components, and products during distribution and when is use. Related controls: PE-3, SA-12, SI-7.	(1) TAMPER RESISTANCE AND DETECTION MULTIPLE PHASES OF SDLC The organization employs anti-tamper technologies and techniques during multiple phases in the system development life cycle including design, development, integration, operations, and maintenance. Supplemental Guidance: Organizations use a combination of hardware and software techniques for tamper resistance and detection. Organizations employ obfuscation and self-checking, for example, to make reverse engineering and modifications more difficult, time-consuming, and expensive for adversaries. Customization of information systems and system components can make substitutions easier to detect and therefore limit damage. Related control: 5A-3. [2) TAMPER RESISTANCE AND DETECTION INSPECTION OF INFORMATION SYSTEMS, COMPONENTS, OR DEVICES The organization inspects [Assignment: organization-defined indications of need for inspection]] to detect tampering. Supplemental Guidance: This control enhancement addresses both physical and logical tampering and is typically applied to mobile devices, notebook computers, or other system components taken out of organization-controlled areas. Indications of need for inspection include, for example, then individuals return from travel to high-risk locations. Related control: St.4.	None
GA-21 DEVELOPER SCREENING	The organization requires that the developer of [Assignment: organization-defined information system, system component, or information system service]: a. Have appropriate access authorizations as determined by assigned [Assignment: organization defined official government duties]; and b. Satisfy [Assignment: organization-defined additional personnel screening criteria].		Because the information system, system component, or information system service may be employed in critical activities essential to the national and/or economic security interests of the United States, organizations have a strong interest in ensuring that the developer is trustworthy. The degree of trust required of the developer may need to be consistent with that of the individuals accessing the information system/component/service once deployed. Examples of authorization and personnel screening criteria include clearance, satisfactory background checks, citizenship, and nationality. Trustworthiness of developers may also include a review and analysis of company ownership and any relationships the company has with entities potentially affecting the quality/reliability of the systems, components, or services being developed. Related controls: PS-3, PS-7.	(1) DEVELOPER SCREENING VALIDATION OF SCREENING The organization requires the developer of the information system, system component, or information system service take [Assignment: organization-defined actions] to ensure that the required access authorizations and screening criteria are satisfied. Supplemental Guidance: Satisfying required access authorizations and personnel screening criteria includes, for example, providing a listing of all the individuals authorized to perform development activities on the selected reference in the contraction of the selected selected reference in the contraction of the selected selected reference in the selected reference in the selected selected reference in the selected selected reference in the selected reference in the selected selected reference in the selected selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected reference in the selected	None
C-1 ISTEM AND COMMUNICATIONS PROTECTION OLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A system and communications protection policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and compliance; and compliance; and compliance; and communications protection policy and associated system and communications protection controls; and b. Reviews and updates the current: 1. System and communications protection policy [Assignment: organization-defined frequency]; and 2. System and communications protection procedures [Assignment: organization-defined frequency]; and	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A18.2.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the SC family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures at the organization level may make the need for system-specific policies and procedures or the policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organizationarisk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
C-7 OUNDARY PROTECTION	The information system: a. Monitors and controls communications at the external boundary of the system and at key internal boundaries within the system; b. Implements subnetworks for publicly accessible system components that are [Selection: physically] separated from internal organizational networks; and c. Connects to external networks or information systems only through managed interfaces consisting of boundary protection devices arranged in accordance with an organizational security architecture.	A13.1.1, A13.1.3, A13.2.1, A14.1.3	Managed interfaces include, for example, gateways, routers, firewalls, guards, network-based malicious code analysis and virtualization systems, or encrypted tunnels implemented within a security architecture (e.g., routers protecting firewalls or application gateways residing on protected subnetworks). Subnetworks that are physically or logically separated from internal networks are referred to as femilitarized zones or DMS. Restricting or prohibiting interfaces within organizational information systems includes, for example, restricting external web traffic to designated web servers within managed interfaces and prohibiting external traffic that appears to be spoofing internal addresses. Organizations consider the shared nature of commercial telecommunications services in the implementation of security controls associated with the use of such services. Commercial telecommunications services are commonly based on network components and consolidated management systems shared by all attached commercial customers, and may also include third party-provided access lines and other service elements. Such transmissions services may represents sources of increased risk despite contract security provisions. Related controls: AC-4, AC-17, CA-3, CM-7, CP-8, IR-4, RA-3, SC-5, SC-13.	(e) Reviews exceptions to the traffic flow policy [Assignment: organization-defined frequency] and removes exceptions that are no longer supported by an explicit mission/business need. Supplemental Guidance: Related control: SC-8. (S) BOUNDARY PROTECTION DENY BY DEFAULT / ALLOW BY EXCEPTION The information system at managed interfaces denies network communications traffic by default and allows network communications traffic by exception (i.e., deny all, permit by exception). Supplemental Guidance: This control enhancement applies to both inbound and outbound network communications traffic. A deny-all, permit-by-exception network communications traffic policy ensures that only those so connections which are essential and approved are allowed. (6) BOUNDARY PROTECTION RESPONSE TO REOGONIZED FAILURES [Withdrawn: Incorporated into SC-7 (18]). (7) BOUNDARY PROTECTION PREVENT SPLIT TUNNELING FOR REMOTE DEVICES The information system, in conjunction with a remote device, prevents the device from simultaneously establishing non-remote connections with the system and communicating via some other connection to resources in external networks. Supplemental Guidance: This control enhancement is implemented within remote device (e.g., notebook computers) through configuration settings to disable split tunneling in those devices, and by preventing those configuration settings from being readily configurable by users. This control enhancement is implemented within the information system by the detection of split tunneling (or of configuration settings that allow split tunneling (or of configuration settings that allow split tunneling (or of configuration settings that allow split tunneling (or of configuration settings that allow split tunneling (or of configuration settings that allow split tunneling) in the remote device, and by prohibiting the connection of if the remote device is using split tunneling might be desirable by remote users to communicate with local information system resources users to communicate	None
:-8 RANSMISSION CONFIDENTIALITY AND TEGRITY	The information system protects the [Selection (one or more): confidentiality; integrity] of transmitted information.	A823,A13.1.1,A13.2.1,A13.2.3,A.14.1.2, A14.1.3	This control applies to both internal and external networks and all types of information system components from which information can be transmitted (e.g., servers, mobile devices, notebook computers, printers, copiers, scanners, facsimile machines). Communication paths outside the physical protection of a controlled boundary are exposed to the possibility of interception and modification. Protecting the confidentiality and/or integrity of organizational information can be accomplished by physical means (e.g., be employing protected distribution systems) or by logical means (e.g., be mploying encryption techniques). Organizations relying on commercial providers offering transmission services as commodity services rather than as fully dedicated services (i.e., services which can be highly specialized to individual customer needs), may find it difficult to obtain the necessary assurances regarding the implementation of needed security controls for transmission confidentiality/integrity, in such situations, organizations determine what types of confidentiality/integrity services are available in standard, commercial telecommunication service packages. If it is infeasible or impractical to obtain the necessary security controls and assurances of control effectiveness through appropriate contracting vehicles, organizations implement appropriate compensating security controls or explicitly accept the additional risk. Related controls: AC-17, PE-4.	Supplemental Guidance: This control enhancement addresses protection against unauthorized disclosure of information. Message externals include, for example, message headers/routing information. This control enhancement prevents the exploitation of message externals and applies to both internal and external networks or links that may be visible to individuals who are not authorized users. Headers/routing information is sometimes transmitted unencrypted because the information is not properly identified by organizations as having significant value costs. Alternative physical safeguards include, for example, protected distribution systems. Related controls: SC-12, SC-13. (4) TRANSMISSION CONFIDENTIALITY AND INTEGRITY CONCEAL / RANDOMIZE COMMUNICATIONS	None
:-12 XYPTOGRAPHIC KEY ESTABLISHMENT AND ANAGEMENT	The organization establishes and manages cryptographic keys for required cryptography employed within the information system in accordance with [Assignment: organization-defined requirements for key generation, distribution, storage, access, and destruction].	3 A10.1.2	Cryptographic key management and establishment can be performed using manual procedures or automated mechanisms with supporting manual procedures. Organizations define key management requirements in accordance with applicable federal laws. Executive Orders, directives, regulations, policies, standards, and guidance specifying appropriate options, levels, and parameters. Organizations manage trust stores to ensure that only approved trust anchors are in such trust stores. This includes certificates with visibility external to organizational information systems and certificates related to the internal operations of systems. Related controls: SC-13, SC-17.	(1) CRYPTOGRAPHIC KEY ESTABLISHMENT AND MANAGEMENT AVAILABILITY The organization maintains availability of information in the event of the loss of cryptographic keys by users. Supplemental Guidance: Escrowing of encryption keys is a common practice for ensuring availability in the event of loss of keys (e.g., due to forgotten passphrase). (2) CRYPTOGRAPHIC KEY ESTABLISHMENT AND MANAGEMENT SYMMETRIC KEYS The organization produces, controls, and distributes symmetric cryptographic keys using [Selection: NIST FIPS-compliant; NSA-approved] key management technology and processes.	The corporate PKI solution should be used where applicable. Consult with the Product Security Head or PI certificate policy owner to get the latest certificate policy (CP).

Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
SC-13 CRYPTOGRAPHIC PROTECTION	The information system implements [Assignment: organization-defined cryptographic uses and type of cryptography required for each use] in accordance with applicable federal laws, Executive Orders, directives, policies, regulations, and standards.		Cryptography can be employed to support a variety of security solutions including, for example, the protection of classified and Controlled Unclassified Information, the provision of digital signatures, and the enforcement of information separation when authorized individuals have the necessary decarances for such information but lack the necessary formal access approvals. Cryptography can also be used to support random number generation and hash generation. Generally applicable cryptography can take the provided FIPS-validated cryptography and NSA-approved cryptography. This control does not impose any requirements on organizations to use cryptography. However, if cryptography is required based on the selection of other security controls, organizations define each type of cryptography required (e.g., protection of classified information: NSA-approved cryptography, provision of digital signatures: FIPS-validated cryptography). Related controls: AC-2, AC-3, AC-7, AC-17, AC-18, AD-9, AD-10, CM-11, CP-9, IA-3, IA-7, MA-4, MP-2, M-9, N-5, SA-5, C-8, SC-12, SC-28, SC-17.	(2) CRYPTOGRAPHIC PROTECTION NSA-APPROVED CRYPTOGRAPHY [Withdrawn: Incorporated into SC-13]. (3) CRYPTOGRAPHIC PROTECTION INDIVIDUALS WITHOUT FORMAL ACCESS APPROVALS [Withdrawn: Incorporated into SC-13]. (4) CRYPTOGRAPHIC PROTECTION IDIGITAL SIGNATURES	None
SC-17 PUBLIC KEY INFRASTRUCTURE CERTIFICATES	The organization issues public key certificates under an [Assignment: organization-defined certificate policy] or obtains public key certificates from an approved service provider.	A.10.1.2	For all certificates, organizations manage information system trust stores to ensure only approved trust anchors an in the trust stores. This control addresses both certificates with visibility external to organizational information systems and certificates related to the internal operations of systems, for example, application-specific time services. Related control: SC-12.	e None	The corporate PKI solution should be used where applicable. Consult with the Product Security Head or PKI certificate policy owner to get the latest certificate policy (CP)
SC-25 THIN NODES	The organization employs [Assignment: organization-defined information system components] with minimal functionality and information storage.	None	The deployment of information system components with reduced/minimal functionality (e.g., diskless nodes and thin client technologies) reduces the need to secure every user endpoint, and may reduce the exposure of information systems, and services to order attacks. Related controls SC-30	None	None
SC-26 HONEYPOTS	The information system includes components specifically designed to be the target of malicious attacks for the purpose of detecting, deflecting, and analyzing such attacks.	None	A honeypot is set up as a decoy to attract adversaries and to deflect their attacks away from the operational systems supporting organizational missions/business function. Depending upon the specific usage of the honeypot, consultation with the Office of the General Counsel before denowment may be needed. Related controls: SC-30. SC-44. SI-3. SI-4.	S None. (1) HONEYOTS DETECTION OF MALICIOUS CODE [Withdrawn: Incorporated into SC-35].	None
SC-28 PROTECTION OF INFORMATION AT REST	The information system protects the [Selection (one or more): confidentiality; integrity] of [Assignment: organization-defined information at rest].	A.8.2.3 (only partially satisfies NIST control	This control addresses the confidentiality and integrity of information at rest and covers user information and system information. Information at rest refers to the state of information when it is located on storage devices as	[1] PROTECTION OF INFORMATION AT REST [CRYPTOGRAPHIC PROTECTION The information system implements cryptographic mechanisms to prevent unauthorized disclosure and modification of [Assignment: organization-defined information] on [Assignment: organization-defined information system components]. 2. Supplemental Guidance: Selection of cryptographic mechanisms is based on the need to protect the confidentiality and integrity of organizational information. The strength of mechanism is commensurate with the security category and/or classification of the information. This control enhancement applies to significant concentrations of digital media in organizational areas designated for media storage and also to limited quantities of media generally associated with information system components in operational environments (e.g., portable storage devices, mobile devices). Organizations have the flexibility to either encrypt all information on storage devices (i.e., full disk encryption) or encrypt specific data structures (e.g., fles, records, or fields). Organizations employing cryptographic mechanisms to protect information at rest also consider cryptographic key management solutions. Related controls: AC-19, SC-12. [2] PROTECTION OF INFORMATION AT REST] OFF-LINE STORAGE The organization removes from online storage and stores off-line in a secure location (Assignment: organization-defined information). Supplemental Guidance: Removing organizational information from online information system storage to off-line storage eliminates the possibility of individuals gaining unauthorized access to the information through a network. Therefore, organizations may choose to move information to off-line organization in online storage.	None
SC-29 HETEROGENEITY	The organization employs a diverse set of information technologies for [Assignment: organization-defined information system components] in the implementation of the information system.	None	Increasing the diversity of information technologies within organizational information systems reduces the impact of potential exploitations of specific technologies and also defends against common mode failures, including those failures induced by supply chain attacks. Diversity in information technologies also reduces the likelihood that the means adversaries use to compromise one information system component will be equally effective against other system components, thus further increasing the adversary work factor to successfully complete planned cyber attacks. An increase in diversity may add complexity and management overhead which could ultimately lead to mistakes and unauthorized configurations. Related controls: SA-12, SA-14, SC-27.	(1) HETEROGENEITY VIRTUALIZATION TECHNIQUES The organization employs virtualization techniques to support the deployment of a diversity of operating systems and applications that are changed [Assignment: organization-defined frequency]. Supplemental Guidance: While frequent changes to operating systems and applications pose configuration management challenges, the changes can result in an increased work factor for adversaries in order to carry out successful cyber attacks. Changing virtual operating systems or applications, provide virtual changes that impode attacker success while reducing configuration management efforts. In addition, virtualization techniques can assist organizations in isolating untrustworthy software and/or software of dubious provenance into confined execution environments.	None
SC-30 CONCEALMENT AND MISDIRECTION	The organization employs [Assignment: organization-defined concealment and misdirection techniques] for [Assignment: organization-defined information systems] at [Assignment: organization-defined time periods] to confuse and mislead adversaries.	None	Concealment and misdirection techniques can significantly reduce the targeting capability of adversaries (i.e., window of opportunity and available attack surface) to initiate and complete cyber attacks. For example, virtualization techniques provide organizations with the ability to disguise information systems, potentially reducing the likelihood of successful attacks without the cost of having multiple platforms. Increased use of concealment/misdirection techniques including, for example, randomness, uncertainty, and virtualization, may sufficiently confuse and mislead adversaries and subsequently increase the risk of discovery and/or exposing tradecraft. Concealment/misdirection techniques may also provide organizations additional time to successfully perform core missions and business functions. Because of the time and effort required to support concealment/misdirection techniques, it is anticipated that such techniques would be used by organizations on a very limited basis. Related controls: SC-26, SC-29, SI-14.	[1] CONCEALMENT AND MISDIRECTION VIRTUALIZATION TECHNIQUES [Withdrawn: Incorporated into Sc-29 (1]]. [2] CONCEALMENT AND MISDIRECTION RANDOMNESS [2] CONCEALMENT AND MISDIRECTION RANDOMNESS The organization employs (Rasignment: organization-defined techniques) to introduce randomness into organizations and assets. Supplemental Guidance: Randomness introduces increased levels of uncertainty for adversaries regarding the actions organizations take in defending against cyber attacks. Such actions may impede the ability of adversaries to correctly target information resources of organizations supporting critical missions/ bytusiness functions. Uncertainty may also cause adversaries to hesitate before initiating or continuing attacks. Misdirection techniques involving randomness include, for example, performing certain routine actions at different times of day, employing different information technologies (e.g., browsers, search engines), using different suppliers, and rotating roles and responsibilities of organizational personnel. [3] CONCEALMENT AND MISDIRECTION CIAKNGE PROCESSING / STORAGE LOCATIONS The organization changes the location of [Assignment: organization-defined processing and/or storage] [Selection: [Assignment: organization-defined time frequency]; at random time intervals]], supplemental Guidance: Adversaries target critical organizational missions/business functions and the information resources supporting those missions and functions while at the same time, trying to minimize exposure of their existence and tradecraft. The static, homogeneous, and deterministic nature of organizational information systems targeted by adversaries, make such systems more susceptible to cyber attacks with less adversary cost and effort to be successful. Changing organizational processing and storage locations (sometimes referred to as migrate defense) addresses the advanced persistent threat [APT] using techniques used as virtualization, distributed processing and replication. This enables organizatio	None
SC-31 COVERT CHANNEL ANALYSIS	The organization: a. Performs a covert channel analysis to identify those aspects of communications within the information system that are potential avenues for covert [Selection (one or more): storage; timing] channels; and b. Estimates the maximum bandwidth of those channels.	None	Developers are in the best position to identify potential areas within systems that might lead to covert channels. Covert channel analysis is a meaningful activity when there is the potential for unauthorized information flows across security domains, for example, in the case of information systems containing export-controlled information and having connections to external networks (i.e., networks not controlled by organizations). Covert channel analysis is also meaningful for multilevel secure (MLS) information systems, multiple security level (MSL) systems, and cross-domain systems. Related controls: AC-3, AC-4, PL-2.	(1) COVERT CHANNEL ANALYSIS TEST COVERT CHANNELS FOR EXPLOITABILITY The organization tests a subset of the identified covert (channels to determine which channels are exploitable. (2) COVERT CHANNEL ANALYSIS MAXIMUM BANDWIDTH The organization reduces the maximum bandwidth for identified covert [Selection (one or more]: storage; timing] channels to [Assignment: organization-defined values]. Supplemental Guidance: Information system developers are in the best position to reduce the maximum bandwidth for identified covert storage and timing channels. (3) COVERT CHANNEL ANALYSIS MEASURE BANDWIDTH IN OPERATIONAL ENVIRONMENTS The organization measures the bandwidth of [Assignment: organization-defined subset of identified covert channels and analysis of identified covert channels and analysis of identified covert channels and analysis of identified covert channels and analysis of identified covert channels and analysis of identified covert channels and analysis of identified covert channel bandwidth in operational environments wersus developmental environments. Measuring covert channel bandwidth in operational environments believed by the organizations to determine how much information can be covertly leaked before such leakage adversely affects organizational missions/business functions. Covert channel bandwidth may be significantly different whe measured in those settings that are independent of the particular environments of operation (e.g., laboratories or development environments).	None
SC-34 NON-MODIFIABLE EXECUTABLE PROGRAMS	The information system at [Assignment: organization-defined information system components]: a. Loads and executes the operating environment from hardware-enforced, read-only media; and b. Loads and executes [Assignment: organization-defined applications] from hardware-enforced, read-only media.	None	The term operating environment is defined as the specific code that hosts applications, for example, operating systems, executives, or monitors including virtual machine monitors (i.e., hypervisors). It can also include certain applications running directly on hardware platforms. Hardware-enforced, read-only media include, for example, Compact Disk-Recordable (CDPA) [Digital Video Disk-Recordable (DDPA) [Digital Video Disk-Recordable (DDPA) and divires and one-time programmable read-only memory. The use of non-modifiable storage ensures the integrity of software from the point of creation of the read-only image. The use of reprogrammable read-only memory can be accepted as read-only media provided: (i) integrity can be adequately protected from the point of initial writing to the insertion of the memory into the information system; and (ii) there are reliable hardware protections against reprogramming the memory while installed in organizational information systems. Related controls: AC-3, SI-7.	(1) NON-MODIFIABLE EXECUTABLE PROGRAMS NO WRITABLE STORAGE The organization employs [Assignment: organization-defined information system components] with no writeable storage that is persistent across component restart or power on/off. Supplemental Guidance: This control enhancement: (i) eliminates the possibility of malicious code insertion via persistent, writeable storage within the designated information system components; and (ii) applies to both fixed and removable storage, with the latter being addressed directly or as specific restrictions imposed through access controls for mobile devices. Related controls: AC-19, MP-7. (2) NON-MODIFIABLE EXECUTABLE PROGRAMS INTEGRITY PROTECTION / READ-ONLY MEDIA The organization protects the integrity of information prived to storage on read-only media and controls the media after such information has been recorded onto the media f Supplemental Guidance: Security safeguards prevent the substitution of media into information systems or the reprogramming of programmable read-only media and controls the media of the complex of the programmable o	None
SC-35 HONEYCLIENTS	The information system includes components that proactively seek to identify malicious websites and/or web-based malicious code.	None	Honeyclients differ from honeypots in that the components actively probe the Internet in search of malicious code (e.g., worms) contained on external websites. As with honeypots, honeyclients require some supporting Isolation measures (e.g., virtualization) to ensure that any malicious code discovered during the search and subsequently executed does not infect organizational information systems. Related controls: SC-26, SC-44, SI-3, SI-4.	None	None



Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
SC-37 OUT-OF-BAND CHANNELS	The organization employs [Assignment: organization-defined out-of-band channels] for the physical delivery or electronic transmission of [Assignment: organization-defined information, information system components, or devices] to [Assignment: organization-defined individuals or information systems].	(SP 800-53, r4, Appendix H) None	Out-of-band channels include, for example, local (nonnetwork) accesses to information systems, network paths physically separate from network paths used for operational traffic, or nonelectronic paths such as the US Postal Service. This is in contrast with using the same channels (i.e., in-band channels) that carry routine operational traffic. Out-of-band channels do not have the same vulnerability (exposure as in-band channels, and hence the confidentiality, integrity, or availability compromises of in-band channels will not compromise the out-of-band channels. Organizations may employ out-of-band channels in the delivery or transmission of many organizational items including, for example, identifiers/authenticators, configuration management his orday may be of the many organizations and firmware, or software, cryptographic key management information, security updates, system/data backups, maintenance information, and malicious code protection updates. Related controls: AC-2, CM-3, CM-5, CM-7, IA-4, I. S. MA-4, S. I. S. J-4, S. I. S. J	(1) OUT-OF-BAND CHANNELS ENSURE DELIVERY / TRANSMISSION The organization employs [Assignment: organization-defined security safeguards] to ensure that only [Assignment: organization-defined information system components, or devices]. Supplemental Guidance: Techniques and/or methods employed by organizations to ensure that only designated information systems or individuals receive particular information, system components, or devices include, for example, sending authenticators via courier service but requiring recipients to show some form of government-issued photographic identification as a condition of receipt.	None
SC-40 WIRELESS LINK PROTECTION	The information system protects external and internal [Assignment: organization-defined wireless links] from [Assignment: organization-defined types of signal parameter attacks or references to sources for such attacks].	None	This control applies to internal and external wireless communication links that may be visible to individuals who are not authorized information system users. Adversaries can exploit the signal parameters of wireless links if such links are not adequately protected. There are many ways to exploit the signal parameters of wireless links to gain intelligence, deny service, or to spoof users of organizational information systems. This control reduces the impact of attacks that are unique to wireless systems. If organizations rely on commercial service providers for transmission services as commodity items rather than as fully dedicated services, it may not be possible to implement this control. Related controls: AC-18, SC-5.	spectrum waveforms used to achieve low probability of detection are not predictable by unauthorized individuals. Mission requirements, projected threats, concept of operations, and applicable legislation, directives,	None
SC-41 PORT AND I/O DEVICE ACCESS	The organization physically disables or removes [Assignment: organization-defined connection ports or input/output devices] on [Assignment: organization-defined information systems or information system components].		Connection ports include, for example, Universal Serial Bus (USB) and Firewire (IEEE 1394). Input/output (I/O) devices include, for example, Compact Disk (CD) and Digital Video Disk (DVD) drives. Physically disabling or removing such connection ports and I/O devices helps prevent exfiltration of information from information system and the introduction of malicious code into systems from those ports/devices.	None	None
SC-42 SENSOR CAPABILITY AND DATA	The information system: a. Prohibits the remote activation of environmental sensing capabilities with the following exceptions: [Assignment: organization-defined exceptions where remote activation of sensors is allowed]; and b. Provides an explicit indication of sensor use to [Assignment: organization-defined class of users].	None	This control often applies to types of information systems or system components characterized as mobile devices, for example, smart phones, tablets, and E-readers. These systems often include sensors that can collect and record data regarding the environment where the system is in use. Sensors that are mebaded within mobile devices include, for example, cameras, microphones, Global Positioning System (GPS) mechanisms, and accelerometers. While the sensors on mobiles devices provide an important function, if activated covertly, such devices can potentially provide a means for adversaries to learn valuable information about individuals and organizations. For example, remotely activating the GPS function on a mobile device could provide an adversary with the ability to track the specific movements of an individual.	(2) SENSOR CAPABILITY AND DATA AUTHORIZED USE The organization employs the following measures: [Assignment: organization-defined measures], so that data or information collected by [Assignment: organization-defined sensors] is only used for authorized purposes. Supplemental Guidance: Information collected by sensors for a specific authorized purpose potentially could be misused for some unauthorized purpose. For example, GPS sensors that are used to support traffic navigation could be misused to track movements of individuals. Measures to mitigate such activities include, for example, additional training to ensure that authorized parties do not abuse their authority, or (in the case where sensor)	None
SC-43 USAGE RESTRICTIONS	The organization: a. Establishes usage restrictions and implementation guidance for [Assignment: organization-defined information system components] based on the potential to cause damage to the information system if used maliciously; and b. Authorizes, monitors, and controls the use of such components within the information system.	None	Information system components include hardware, software, or firmware components (e.g., Voice Over Internet Protocol, mobile code, digital copiers, printers, scanners, optical devices, wireless technologies, mobile devices). Related controls: CM-6, SC-7.	None	None
SC-44 DETONATION CHAMBERS	The organization employs a detonation chamber capability within [Assignment: organization-defined information system, system component, or location].	None	Detonation chambers, also known as dynamic execution environments, allow organizations to open email attachments, execute untrusted or suspicious applications, and execute Universal Resource Locator (URL) requests in the safety of an isolated environment or virtualized sandbox. These protected and isolated execution environments provide a means of determining whether the associated attachments/applications contain malicious code. While related to the concept of deception nets, the control is not intended to maintain a long-term environment in which adversaries can operate and their actions can be observed. Rather, it is intended to quickly identify malicious code and reduce the likelihood that the code is propagated to user environments of operation (or prevent such propagation completely). Related controls: SC7, SC2, SC3, SC3, SC3.0.	S None	None
SI-1 SYSTEM AND INFORMATION INTEGRITY POLICY AND PROCEDURES	The organization: a. Develops, documents, and disseminates to [Assignment: organization-defined personnel or roles]: 1. A system and information integrity policy that addresses purpose, scope, roles, responsibilities, management commitment, coordination among organizational entities, and compliance; and 2. Procedures to facilitate the implementation of the system and information integrity policy and associated system and information integrity controls; and b. Reviews and updates the current: 1. System and information integrity policy [Assignment: organization-defined frequency]; and 2. System and information integrity procedures [Assignment: organization-defined frequency].	A5.1.1, A5.1.2, A6.1.1, A12.1.1, A18.1.1, A18.2.2	This control addresses the establishment of policy and procedures for the effective implementation of selected security controls and control enhancements in the SI family. Policy and procedures reflect applicable federal laws, Executive Orders, directives, regulations, policies, standards, and guidance. Security program policies and procedures at the organization level may make the need for system-specific policies and procedures unnecessary. The policy can be included as part of the general information security policy for organizations or conversely, can be represented by multiple policies reflecting the complex nature of certain organizations. The procedures can be established for the security program in general and for particular information systems, if needed. The organization risk management strategy is a key factor in establishing policy and procedures. Related control: PM-9.		None
SI-2 FLAW REMEDIATION	The organization: a. Identifies, reports, and corrects information system flaws; b. Tests software and firmware updates related to flaw remediation for effectiveness and potential side effects before installation; c. Installs security-relevant software and firmware updates within [Assignment: organization-defined time period] of the release of the updates; and d. Incorporates flaw remediation into the organizational configuration management process.	A12.6.1, A.14.2.2, A.14.2.3, A.16.1.3	organizations may determine that the testing of software and/or firmware updates is not necessary or practical, for example, when implementing simple anti-virus signature updates. Organizations may also consider in testing decisions, whether security-relevant software or firmware updates are obtained from authorized sources with	monitoring the organization-defined, centrally managed flaw remediation security controls. (2) FLAW REMEDIATION AUTOMATED FLAW REMEDIATION STATUS The organization employs automated mechanisms [Assignment organization-defined frequency] to determine the state of information system components with regard to flaw remediation. Supplemental Guidance: Related controls: CM-6, SI-4. (3) FLAW REMEDIATION TIME TO REMEDIATE FLAWS / BENCHMARKS FOR CORRECTIVE ACTIONS The organization: (a) Measures the time between flaw identification and flaw remediation; and (b) Establishes [Assignment: organization-defined benchmarks] for taking corrective actions. Supplemental Guidance: This control enhancement requires organizations to determine the current time it takes on the average to correct information system flaws after such flaws have been identified, and subsequently establish organizational benchmarks (Let, time frames) for taking corrective actions. Benchmarks can be established by type of flaw and/or severity of the potential vulnerability if the flaw can be exploited. (4) FLAW REMEDIATION AUTOMATED PATCH MANAGEMENT TOOLS [Withdraws: Incorporated into SI-2].	None



Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	ISO/IEC 27001 Controls that fulfill the NIST Control	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
3 ALICIOUS CODE PROTECTION	The organization: a. Employs mallicious code protection mechanisms at information system entry and exit points to detect and eradicate malicious code; b. Updates malicious code protection mechanisms whenever new releases are available in accordance with organizational configuration management policy and procedures; c. Configures malicious code protection mechanisms to: 1. Perform periodic scans of the information system [Assignment: organization-defined frequency] and real-time scans of files from external sources at [Selection (one or more); endpoint; network entry/exit points] as the files are downloaded, opened, or executed in accordance with organizational security policy; and 2. [Selection (one or more); block malicious code; quarantine malicious code; send alert to administrator; [Assignment: organization-defined action]] in response to malicious code detection; and d. Addresses the receipt of false positives during malicious code detection and eradication and the resulting potential impact on the availability of the information system.	(SP 800-53, r4, Appendix H)	Information system entry and exit points include, for example, firewalls, electronic mail servers, web servers, proxy servers, remote-access servers, workstations, notebook computers, and mobile devices. Malicious code includes, for example, vinces, worms, Trojan horses, and spyware. Malicious code can also be encoded in various formats (e.g., UUENCODE, Unicode), contained within compressed or hidden files, or hidden in files using steganography. Malicious code can be transported by different means including, for example, web accesses, electronic mail, electronic mail attachments, and portable storage devices. Malicious code insertions occur through the exploitation of information system vulnerabilities. Malicious code protection mechanisms include, for example, anti-virus signature definitions and reputation-based technologies. A variety of technologies and methods exist to limit or eliminate the effects of malicious code. Pervasive configuration management and comprehensive software integrity controls may be effective in preventing execution of unauthorized code. In addition to commercial off-the-shelf software, malicious code may also be present in custom-built software. This could include, for example, logic bombs, back doors, and other types of cyber attacks that could affect organizational missions/business functions. Traditional malicious code protection mechanisms cannot always detect such code. In these situations, organizations rely instead on other safeguards including, for example, secure coding practices, configuration management and control, trusted procurement processes, and monitoring practices to help ensure that software	(1) MALICIOUS CODE PROTECTION CENTRAL MANAGEMENT The organization centrally manages malicious code protection mechanisms. Supplemental Guidance: Central management is the organization-wide management and implementation of malicious code protection mechanisms. Central management includes planning, implementing, assessing, authorizing, and monitoring the organization-defined, centrally managed flaw malicious code protection security controls. Related controls: AU-2, SI-8. (2) MALICIOUS CODE PROTECTION AUTOMATIC UPDATES The information system automatically updates malicious code protection mechanisms. Supplemental Guidance: Malicious code protection mechanisms include, for example, signature definitions. Due to information system integrity and availability concerns, organizations give careful consideration to the methodology used to carry out automatic updates. Related control: SI-8. (3) MALICIOUS CODE PROTECTION NON-PRIVILEGED USERS (4) MALICIOUS CODE PROTECTION UPDATES ONLY BY PRIVILEGED USERS The information system updates malicious code protection mechanisms only when directed by a privileged user. Supplemental Guidance: This control enhancement may be appropriate for situations where for reasons of security or operational continuity, updates are only applied when selected/approved by designated organizational personnel. Related controls: AC-6, CM-5. (5) MALICIOUS CODE PROTECTION POPATABLE STORAGE DEVICES (Withdrawn: Incorporated into MP-7].	None
4 FORMATION SYSTEM MONITORING	The organization: a. Monitors the information system to detect: 1. Attacks and indicators of potential attacks in accordance with [Assignment: organization-defined monitoring objectives]: and 2. Unauthorized local, network, and remote connections; b. Identifies unauthorized use of the information system through [Assignment: organization-defined techniques and methods]; c. Deploys monitoring devices: 1. Strategically within the information system to collect organization-determined essential information; and 2. At ad hoc locations within the system to track specific types of transactions of interest to the organization; d. Protects information obtained from intrusion-monitoring tools from unauthorized access, modification, and deletion; e. Heightens the level of information system monitoring activity whenever there is an indication of increased risk to organizational operations and assets, individuals, other organizations, or the Nation based on law enforcement information, intelligence information, or other credible sources of information f. Obtains legal opinion with regard to information system monitoring activities in accordance with applicable federal laws, Executive Orders, directives, policies, or regulations; and g. Provides [Assignment: organization-defined information system monitoring information] to [Assignment: organization-defined frequency]].	None	Information system monitoring includes external and internal monitoring. External monitoring includes the observation of events occurring at the information system boundary (i.e., part of perimeter defense and boundary protection). Internal monitoring includes the observation of events occurring within the information system. Organizations can monitor information systems, for example, by observing within the information system. Organizations can monitor information systems, for example, by observing udit activities in real time or by observing other system aspects such as access patterns, characteristics of access, and other actions. The monitoring objectives may guide determination of the events. Information system monitoring capability is cahieved through a variety of tools and techniques (e.g., intrusion detection systems, intrusion prevention systems, malicious code protection software, scanning tools, audit record monitoring software, network monitoring software, Extrategic locations for monitoring devices include, for example, selected perimeter locations and near server farms supporting critical applications, with such devices typically being employed at the managed interfaces associated with controls SC-7 and Ac-17. Einstein network monitoring devices from the Department of Homeland Security can also be included as monitoring devices. The granularity of monitoring information collected is based on organizational monitoring objectives and the capability of information systems to support such objectives. Specific types of transactions of interest include, for example, Hyper Text Transfer Protocol (HTTP) traffic that bypasses HTTP proxies. Information system monitoring is an integral part of organizational continuous monitoring and incident response programs. Output from system monitoring serves as input to continuous monitoring and incident response programs. Output from system monitoring sorves as input to continuous monitoring and incident response programs. An etwork connection is any connection with a	The information system minitor System MonitorioRing (System-Aprenated to information system intrusion detection system.) (2) INFORMATION SYSTEM MONITORING (SYSTEM APPENDENTISUSION DETECTION SYSTEM MONITORING) (SYSTEM APPENDENTISUSION DETECTION SYSTEM MONITORING) (AUTOMATED TOOLS FOR REAL-TIME ANALYSIS The organization connects and configures individual intrusion detection tools into an information system. (2) INFORMATION SYSTEM MONITORING (AUTOMATED TOOLS FOR REAL-TIME ANALYSIS The organization employs automated tools to support near real-time analysis of events. Supplemental Guidance: Automated tools include, for example, host-based, network-based, transport-based, or storage-based event monitoring tools or Security Information and Event Management (SIEM) technologies that provide real time analysis of alerts and/or notifications generated by organizational information systems. (3) INFORMATION SYSTEM MONITORING (INTOMATED TOOL) INTEGRATION The organization employs automated tools to integrate intrusion detection tools into access control and flow control mechanisms for rapid response to attacks by enabling reconfiguration of these mechanisms in support of attacks loadinon system monitoris inbound and outbound communications traffic (Assignment organization-defined frequency) for unusual or unauthorized activities or conditions. Supplemental Guidance: Unusual/unauthorized activities or conditions related to information system inbound and outbound communications traffic (Assignment organization-defined presence of malicious code within organizational information systems or signaling to external information system inbound and outbound communications traffic (Assignment organization-defined compromise components. (5) INFORMATION SYSTEM MONITORING (SYSTEM-GENERATED ALERTS The information system enderty and a variety of sources, including, for example, audit records or inputs from malicious code protection mechanisms, intrusion detection or prevention mechanisms, or boundary protection devices such as fire	None
-5 CCURITY ALERTS, ADVISORIES, AND RECTIVES	The organization: a. Receives information system security alerts, advisories, and directives from [Assignment: organization-defined external organizations] on an ongoing basis; b. Generates internal security alerts, advisories, and directives as deemed necessary; c. Disseminates security alerts, advisories, and directive sto: [Selection (one or more): [Assignment: organization-defined personnel or roles]; [Assignment: organization-defined elements within the organization-jt [Assignment: organization-defined external organizations]; and d. Implements security directives in accordance with established time frames, or notifies the issuing organization of the degree of noncompliance.	A.6.1.4 (only partially satisfies NIST control)	The United States Computer Emergency Readiness Team (US-CERT) generates security alerts and advisories to maintain situational awareness across the federal government. Security directives are issued by OMB or other designated organizations with the responsibility and authority to issue such directives. Compliance to security directives is essential due to the critical nature of many of these directives and the potential immediate adverse effects on organizational operations and assets, individuals, other organizations, and the Nation should the directives not be implemented in a timely manner. External organizations include, for example, external mission/business partners, supply chain partners, external service providers, and other peer/supporting organizations. Related control: SI-2.	to ensure the confidentiality of communications traffic is paramount; for others, mission-assurance is of greater concern. Organizations determine whether the visibility requirement applies to internal encrypted traffic, (1) SECURITY ALERTS, ADVISORIES, AND DIRECTIVES AUTOMATED ALERTS AND ADVISORIES The organization employs automated mechanisms to make security alert and advisory information available throughout the organization. Supplemental Guidance: The significant number of changes to organizational information systems and the environments in which those systems operate requires the dissemination of security-related information to a variety of organizational entities that have a direct interest in the success of organizational missions and business functions must make a direct interest in the success of organizational missions and business functions must no provided by the security alerts and advisories, changes may be required at one or more of the three tiers related to the management of information security risk including the governance level, mission/business process/enterprise architecture level, and the information system level.	
-6 CURITY FUNCTION VERIFICATION	Issuing organization of the degree of noncompliance. The information system: a Verifies the correct operation of [Assignment: organization-defined security functions]; b. Performs this verification [Selection (one or more): [Assignment: organization-defined system transitional states]; upon command by user with appropriate privilege; [Assignment: organization-defined frequency]]; c. Notifies [Assignment: organization-defined personnel or roles] of failed security verification tests; and d. [Selection (one or more): shuts the information system down; restarts the information system; [Assignment: organization-defined alternative action(s)]] when anomalies are	None	Transitional states for information systems include, for example, system startup, restart, shutdown, and abort. Notifications provided by information systems include, for example, electronic alerts to system administrators, messages to local computer consoles, and/or hardware indications such as lights. Related controls: CA-7, CM-6.	(1) SECURITY FUNCTION VERIFICATION NOTIFICATION OF FAILED SECURITY TESTS [Withdrawn: Incorporated into SI-6]. (2) SECURITY FUNCTION VERIFICATION AUTOMATION SUPPORT FOR DISTRIBUTED TESTING The information system implements automated mechanisms to support the management of distributed security testing. Supplemental Guidance: Related control. SI-2. (3) SECURITY FUNCTION VERIFICATION REPORT VERIFICATION RESULTS The organization reports the results of security function verification to [Assignment: organization reports the results of security function verification to results include, for example, senior information security officers, information system security officers. Related controls: SA-12, SI-4, SI-5.	None



Control (NICE on con F24)	Control Specifics (CD 000 F31)	ISO/IEC 27001 Controls that fulfill	Supplemental Cuid (CD 000 CD)	Control Enhancer (CD 000 Ed. 1)	Additional Strukov Coldanas Concess
Control (NIST SP 800-53, r4)	Control Specifics (SP 800-53, r4)	the NIST Control (SP 800-53, r4, Appendix H)	Supplemental Guidance (SP 800-53, r4)	Control Enhancements (SP 800-53, r4)	Additional Stryker Guidance for Control
SI-7 SOFTWARE, FIRMWARE, AND INFORMATION INTEGRITY	The organization employs integrity verification tools to detect unauthorized changes to [Assignment: organization-defined software, firmware, and information].	None	Unauthorized changes to software, firmware, and information can occur due to errors or malicious activity (e.g., tampering). Software includes, for example, operating systems (with key internal components such as kernels, drivers), middleware, and applications. Firmware includes, for example, the Basic Input Output System (BIOS). Information includes metadata such as security attributes associated with information. State-of-the-practice integrity-checking mechanisms (e.g., parity checks, cyclical redundancy checks, cryptographic hashes) and associated tools can automatically monitor the integrity of information systems and hosted applications. Related controls: SA-12, SC-8, SC-13, S1-3.	(1) SOFTWARE, FIRMWARE, AND INFORMATION INTEGRITY INTEGRITY CHECKS The information system performs an integrity check of [Assignment: organization-defined software, firmware, and information] [Selection (one or more): at startup; at [Assignment: organization-defined transitional states or security-relevant events]; [Assignment: organization-defined frequency]]. Supplemental Guidance: Security-relevant events include, for example, but definition of a new threat to which organizational information systems are susceptible, and the installation of new hardware, software, or firmware. Transitional states include, for example, system startup, restart, shutdown, and abort. (2) SOFTWARE, FIRMWARE, AND INFORMATION INFEGRITY AUTOMATEON DYFIFICATIONS OF INTEGRITY VIOLATIONS The organization employs automated tools that provide notification to [Assignment: organization-defined personnel or roles] upon discovering discrepancies during integrity verification. Supplemental Guidance: The use of automated tools to report integrity violations and to notify organizational personnel in a timely matter is an essential precursor to effective risk response. Personnel having an interest in integrity violations include, for example, mission/business owners, information system owners, systems administrators, software developers, systems integrators, and information security officers. (3) SOFTWARE, FIRMWARE, AND INFORMATION INTEGRITY CENTRALLY-MANAGED INTEGRITY VIOLATIONS The report of the controls: AU-3, S.1-2, S.1-8. (4) SOFTWARE, FIRMWARE, AND INFORMATION INTEGRITY AUTOMATED RESPONSE TO INTEGRITY VIOLATIONS The information system automatically [Selection (one or more): shuts the information system; implements [Assignment: organization-defined security safeguards]] when integrity violations are descovered. Supplemental Guidance: Organizations may define different integrity checking and anomaly responses; (1) by type of information system; implements organization-defined security safeguards within organization in informat	None
SI-8 SPAM PROTECTION	The organization: a. Employs spam protection mechanisms at information system entry and exit points to detect and take action on unsolicited messages; and b. Updates spam protection mechanisms when new releases are available in accordance with organizational configuration management policy and procedures.	None	Information system entry and exit points include, for example, firewalls, electronic mail servers, web servers, proxy servers, remote-access servers, workstations, mobile devices, and notebook/laptop computers. Spam can be transported by different means including, for example, electronic mail, electronic mail attachments, and web accesses. Spam protection mechanisms include, for example, signature definitions. Related controls: AT-2, AT-3, SC-5, SC-7, SI-3.	monitoring the organization-defined, centrally managed spam protection security controls. Related controls: AU-3, SI-2, SI-7. [2] SPAM PROTECTION AUTOMATIC UPDATES The information system automatically undates coam protection mechanisms.	None
SI-10 INFORMATION INPUT VALIDATION	The information system checks the validity of [Assignment: organization-defined information inputs].	None	Inecking the valid syntax and semantics of information system inputs (e.g., character set, length, numerical range, and acceptable values) verifies that inputs match specified definitions for format and content. Software applications typically follow well-defined protocols that use structured messages (i.e., commands or queries) to communicate between software modules or system components. Structured messages can contain raw or unstructured data interspersed with metadata or control information. If software applications use attacker could insert malicious commands or special characters that can cause the data to be interpreted as control information or metadata. Consequently, the module or component that receives the tainted output will perform the wrong operations or otherwise interpret the data incorrectly. Prescreening inputs prior to passing to interpreters prevents the content from being unintentionally interpreted as commands. Input validation helps to ensure accurate and correct inputs and prevent attacks such as cross-site scripting and a variety of injection attacks.	(1) INFORMATION INPUT VALIDATION MANUAL OVERRIDE CAPABILITY The information system:	
SI-11 ERROR HANDLING	The information system: a. Generates error messages that provide information necessary for corrective actions without revealing information that could be exploited by adversaries; and b. Reveals error messages only to [Assignment: organization-defined personnel or roles]. The organization handles and retains information within the information system and	None	Organizations carefully consider the structure/content of error messages. The extent to which information systems are able to identify and handle error conditions is guided by organizational policy and operational requirements. Information that could be exploited by adversaries includes, for example, erroneous logon attempts with password entered by mistake as the username, mission/business information that can be derived from (if not stated explicitly by) information recorded, and personal information such as account numbers, social security numbers, and credit card numbers. In addition, error messages may provide a covert channel for transmitting information. Related controls: Alt-2, Alt-3, SC-31. Information handling and retention requirements cover the full life cycle of information, in some cases extending		None
SI-12 INFORMATION HANDLING AND RETENTION	The organization handles and retains information within the information system and information output from the system in accordance with applicable federal laws, Executive Orders, directives, policies, regulations, standards, and operational requirements.	None	Information handling and retention requirements cover the full life cycle of information, in some cases extending beyond the disposal of information systems. The National Archives and Records Administration provides guidance on records retention. Related controls: AC-16, AU-5, AU-11, MP-2, MP-4.	None	None
SI-15 INFORMATION OUTPUT FILTERING	The information system validates information output from [Assignment: organization-defined software programs and/or applications] to ensure that the information is consistent with the expected content.	None	Certain types of cyber attacks (e.g., SQL injections) produce output results that are unexpected or inconsistent with the output results that would normally be expected from software programs or applications. This control enhancement focuses on detecting extraneous content, preventing such extraneous content from being displayed, and alerting monitoring tools that anomalous behavior has been discovered. Related controls: SI-3, SI-4.	None	None
SI-17 FAIL-SAFE PROCEDURES	The information system implements [Assignment: organization-defined fail-safe procedures] when [Assignment: organization-defined failure conditions occur].	None	Failure conditions include, for example, loss of communications among critical system components or between system components and operational facilities. Fail-safe procedures include, for example, alerting operator personne and providing specific instructions on subsequent steps to take (e.g., do nothing, reestablish system settings, shut down processes, restart the system, or contact designated organizational personnel). Related controls: CP-12, CP-	el None	None

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PRODUCT SECURITY STANDARD ASSESSMENT - Privacy by Design (PbD) Baseline Requirements Definition of key privacy terms and additional Privacy by Design explanations may be located in D0000061607, Privacy by Design.									
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PbD Family and Purpose	PbD Sub-element and Purpose	PbD Control	PbD Baseline Requirements						
1. Authority & Purpose This family ensures that organizations: (i) identify the legal bases that authorize a	1.1 Authority to collect Specification of Controller/Processor (GDPR), Covered Entity/Business Associate (HIPAA), consent, data flows	1.1.1 Authority to collect in GDPR	(1) When SYK is a controller, determine the Legal basis (IP-1 Consent from NIST SP 800-53, or any other) and provide a Privacy notice to the data subject (TR-1 Privacy Notice from NIST SP 800-53). If there are data exchanges with other parties, appropriate Data Processing Agreements between SYK and those parties shall be established. (1.a.) When SYK is a joint controller together with another party, create appropriate Joint Controller Agreements between Stryker and other party regarding the responsibilities for the PI flowing through the device. (1.b.) When SYK is a controller in common with another controller, no Data Processing Agreement is required as they operate as separate parties. (1.c.) In all above cases legal or compliance shall be contacted for further advise. (2.) When SYK is a processor on behalf of a hospital, create appropriate Data Processing Agreements between Stryker and Customer regarding the responsibilities for the PI flowing through the device. (2.a.) When SYK is a sub-processor on behalf of another party, ensure activities are aligned with data protection standard agreed in Contractual Agreements between Controller and Processor.						
particular personal information (PI) collection or		1.1.2 Authority to collect in HIPAA	(1) When SYK is a covered entity (very unlikely) contact legal in order to clarify specific requirements. (2) When SYK is a business associate establish a Business Associate Agreement.						
activity that impacts privacy; and (ii) specify in their notices the purpose(s) for which PI is collected.		1.1.3 Authority to collect in architectural diagrams	(1) A system architecture visual shall depict the data flow of privacy data through major components and interfaces of the device. (2) An architectural context diagram shall depict how the device will be embedded in a customer environment and how the above defined roles apply in this device application context. (3) The system architecture visual and the architectural context diagram shall also be documented in the Security Operations Manual (SOM) for customer information reasons without disclosing proprietary information.						
	1.2 Purpose specification	1.2.1 Purpose specification in architectural diagrams	The main purpose shall be explicitly defined in an architectural document.						
	Personal data may only be collected for specified, explicit and legitimate purposes. Define purpose of collection. Ensure data flow structure supports	1.2.2 Purpose limitation	The data and functional structure of the device shall guarantee the purpose limitations and shall not allow the system to be used outside the scope of the purpose definition. This means that the personal information acquired and kept by the device shall be restricted to information which is necessary to fulfill the stated purpose.						
	only defined purpose.	1.2.3 Purpose definition in SOM	The purpose definition shall be documented in the Security Operations Manual (SOM).						
	2.1 Governance & Privacy Program Senior roles are appointed to safeguard Privacy & Security	This sub-element has no baseline requirements for the design of individual products. It relates to systemic or orgnizational privacy requirements.							
	2.2 Privacy Impact & Risk Assessment Standard methods are used to conduct risk assessments & mitigate risk	2.2.1 Data Privacy Impact Assessment	A (Data) Privacy Impact Assessment (DPIA) shall be performed. The outcome of the privacy impact assessment may need to be considered in (a) the security risk assessment, or (b) any other design output documentation for further specification of data protection controls.						
	2.3 Privacy Requirements for Contractors and Service Providers Contracts are used to establish requirements for contractors and providers	This sub-element has no baseline requirements for the design of individual products. It relates to systemic or organizational privacy requirements.							
2. Accountability, Audit, Risk Management	2.4 Privacy Monitoring and Auditing Auditing program defines responsibilities	This sub-element has no baseline requirements for the design of individual products. It relates to systemic or organizational privacy requirements.							
effective controls for governance, monitoring, risk	2.5 Privacy Awareness & Training The workforce is trained on the requirements	This sub-element has no baseline requirements for the design of individual products. It relates to systemic or organizational privacy requirements.							
management, and assessment to demonstrate that organizations are complying with applicable orivacy protection requirements and minimizing	2.6 Privacy Reporting Reporting to senior management, and to authorities where required	This sub-element has no baseline requireme	ents for the design of individual products. It relates to systemic or orgnizational privacy requirements.						
overall privacy risk.		2.7.1 Data minimization	Use the least amount of Personal information in order to fulfill the defined purpose and control access based on 'need to know' and/or roles and responsibilities. Consider the use of independent certified partners to verify.						
	2.7 Privacy Enhanced System Design & Development	2.7.2 Pseudonymization	Ensure with appropriate techniques that critical (health) information cannot be related to its related individual without additional information. Consider the use of independent certified partners to verify.						
	Use of access controls, anonymization, pseudonymization, and/or encryption	2.7.3 Anonymization	Ensure with appropriate techniques and in a statistical valid manner that critical (health) information cannot be related to its related individual in any way. Consider the use of independent certified partners to verify.						



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PbD Family and Purpose	PbD Sub-element and Purpose	PbD Control	PbD Baseline Requirements
-	•	2.7.4 Encryption	Ensure that data at rest and data in transition is encrypted. Consider the use of independent certified partners to verify.
	2.8 Accounting of Disclosure Use of data inventory, registration of disclosures	This sub-element has no baseline requireme	ents for the design of individual products. It relates to systemic or orgnizational privacy requirements.
3. Data Quality & Integrity	3.1 Data Quality	3.1.1 Data Quality Mechanism	A mechanism shall ensure that data is kept up to date, discover mistaken data, and have the ability to correct data.
This family enhances public confidence that any personally identifiable information (PI) collected and maintained by organizations is accurate,	Ensure mechanisms exist to keep data up to date, discover mistaken data and have the ability to correct data.	3.1.2 Data integrity in the SOM	The Security Operations Manual (SOM) shall contain appropriate instructions when customer involvement is needed to maintain data integrity.
relevant, timely, and complete for the purpose for which it is to be used, as specified in public notices.	3.2 Data Integrity & Data Integrity Board Establish methods to ensure confidentiality, integrity and availability of personal information and flags for vulnerabilities	3.2.1 Additional Data Processing Functions for Integrity	In order to maintain the integrity of PI, suitable data processing functionality may be considered. For instance, an automatic audit function can be used to flag relevant changes to data or other specific requirements of "Electronic Code of Federal Regulations, Part 11" may apply.
4. Data Minimization & Retention	4.1 Minimization of personally identifiable Information Collect only minimal amount of data		designed so the it only acquires and keeps personal information to the extent that is needed to fulfill the purpose quires the purpose definition to be documented in the SOM. Since these requirements are already stated in 1.2.2 and again within family 4.1.
This family helps organizations implement the data minimization and retention requirements to		4.2.1 Enabling deletion of data	Include functionality that allows data deletion to ensure that data is not kept longer than defined in the purpose specification.
collect, use, and retain only personal information (PI) that is relevant and necessary for the purpose for which it was originally collected. Organizations	Only keep data for duration required by law and as needed for the purpose;	4.2.2 Time Stamp Identification	Mark personal data with time stamp information to enable it to be selected for deletion on the basis of when it was acquired or stored.
retain PI for only as long as necessary to fulfill the purpose(s) specified in public notices and in accordance with approved record retention	delete afterward	4.2.3 Data Disposal in SOM	Include a statement in the Security Operations Manual (SOM) to ensure that the customer follows applicable data minimization rules and to explain how data my be deleted.
schedules.	4.3 Minimization of PII used in Testing, Training, and IP Use of minimal identifiable data for testing	4.3.1 Use of Dummy Data for Testing	When test data is needed, dummy data shall be specified and used instead of personal data from real persons. This may consist of de-identified data or 'fake' data not derived from real personal data.
	5.1 Consent	5.1.1 Consent if Controller	If Stryker is defined as data controller for this product, consider setting up the workflow such that a patient consent degree is required before any data processing starts.
5. Individual Participation & Redress	If Stryker acts as a controller and collects PHI, consent from individuals may be necessary	5.1.2 Consent if Processor	If Stryker is defined as data processor for this product, consider adding a warning statement on the device with a message similar to, "This product processes personal data. The surgeon is responsible for obtaining patient consent for product use when appropriate."
This family addresses the need to make individuals active participants in the decision-making process regarding the collection and use of	5.2 Individual Access	5.2.1 Functionality for Individual Data Access Requests	The device shall be able to support requests of individuals for access to their Personal Information. Note: Patients do not need to get access to the device. A machine-readable (soft copy) export summary (pdf) could
providing individuals with access to PII and the ability to have their PII corrected or amended, as	5.3 Redress		satisfy this requirement. Ensure that PI from others is redacted. The device shall be able to support requests of individuals for deletion, restriction of processing, revision or portability of their Personal Information.
abmity to have their Pit corrected or amended, as appropriate, the controls in this family enhance public confidence in organizational decisions made based on the PII.	Responding to individuals' requests for deletion, restriction, revision, etc. of their PI	5.3.1 Functionality for Individual Data Activity Requests	Note: Patients do not need to get access to the device or be able to perform the modifications themselves. A confirmation of deletion, continued restricted use, revision/correction of data or portable copy could satisfy this
	5.4 Complaint or request management Responding to complaints and general requests	requirement. This sub-element has no baseline requirements for the design of individual products. It relates to systemic or orgnizational privacy requirements.	
6. Security This family supplements the security controls to ensure that technical, physical, and administrative safeguards are in place to protect personally identifiable information (PII) collected or maintained by organizations against loss,	6.1 Inventory of Personally Identifiable Information	This sub-element's requirements are covere	ed by the architectural and data flow requirements in sub-element 1.2 Purpose Specification.



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PbD Family and Purpose	PbD Sub-element and Purpose	PbD Control	PbD Baseline Requirements	
coordination with information security personnel and in accordance with the existing Risk Management Framework.	Incident response plans, breach notification assessment and methods	This sub-element has no baseline requireme	ents for the design of individual products. It relates to systemic or orgnizational privacy requirements.	
	7.1 Privacy Notice Where Stryker is a data controller (GDPR) it needs to inform individuals about its PI collection and privacy practices through a privacy statement	7.1.1 Transparency if Controller	If Stryker is defined as data controller for this product, consider setting up the workflow such that a patient is informed about the data collection before any data processing starts.	
This family ensures that organizations provide public notice of their information practices and	7.2 System of Records Any Privacy Notices and declared data inventories to authorities should be kept up to date	This sub-element has no baseline requirements for the design of individual products. It relates to systemic or orgnizational privacy requirements.		
the privacy impact of their programs and activities.	7.3 Dissemination of Privacy program information Materials should be developed and disseminated in the organization which demonstrate accountable privacy practices, including a Privacy Policy	This sub-element has no baseline requireme	ents for the design of individual products. It relates to systemic or orgnizational privacy requirements.	
8. Use Limitation This family ensures that organizations only use personal information (PI) either as specified in their public notices, in a manner compatible with those specified purposes, or as otherwise	8.1 Internal Use Internal Privacy Policy, in which data usage is aligned with privacy policy and privacy notices and is otherwise addressed, or updates made to privacy policy or privacy notices		If Stryker is defined as data controller for this product, the legal or compliance department shall be contacted for further advice concerning internal use.	
permitted by law. Implementation of the controls in this family will ensure that the scope of PI use is limited accordingly.	8.2 Information Sharing with Third Parties Privacy policy and notices and contracts include information on information sharing practices	This sub-element has no baseline requireme	ents for the design of individual products. It relates to systemic or orgnizational privacy requirements.	